CHAVEZ & GERTLER LLP
Mark A. Chavez (SBN 090858)
Christian Schreiber (SBN 245597)
42 Miller Avenue
Mill Valley, California 94941
Telephone: (415) 381-5599
Facsimile: (415) 381-5572
mark@chavezgertler.com
christian@chavezgertler.com

BROWN | POORE LLP
Scott A. Brown (SBN 177099)
David M. Poore (SBN 192541)
1350 Treat Boulevard, Suite 400
Walnut Creek, California 94597
Telephone: (925) 943-1166
Facsimile: (925) 943-1164
sbrown@bplegalgroup.com
dpoore@bplegalgroup.com

Attorneys for Qui Tam Plaintiffs

EDL

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, *ex rel.* ERIN HAYES AND RICHARD PONDER, Qui Tam Plaintiffs and Relators, v. COVIDIEN, INC., Defendant.	**Case No.** CV 14 1511 **COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729 *et seq.* AND 31 U.S.C. 3130(h); CALIFORNIA FALSE CLAIMS ACT, GOV'T CODE. § 12650 *et seq.*** **FILED IN CAMERA AND UNDER SEAL** **JURY TRIAL DEMANDED**

Plaintiffs and *qui tam* relators Erin Hayes and Richard Ponder, through their attorneys Chavez & Gertler LLP and Brown Poore LLP, for their Complaint against Covidien, Inc., allege as follows:

INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the State of California arising from false and/or fraudulent statements, records, and claims made and caused to be made by Defendant Covidien, Inc. ("Covidien") and/or its agents, employees, and co-conspirators in violation of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, ("the FCA" or "the Act") and the California False Claims Act, Cal. Gov't C. § 12650 *et seq.* ("the CFCA").

2. The Plaintiff Relators bring this action in their own name to obtain the relief needed to make them whole from the damages they suffered from violations of 31 U.S.C. § 3130(h). Plaintiff Relators were terminated in retaliation for reporting Covidien's unlawful conduct. They are an "original source" of the information on which the allegations contained herein are based as that term is defined in 31 U.S.C. § 3730(e)(4).

3. As alleged herein, Covidien knowingly defrauded the federal government and the State of California by submitting, or causing to be submitted, false and fraudulent claims in connection with Medicare, Medicaid and other federal and California health care programs.

BACKGROUND AND SUMMARY OF CLAIMS

4. Covidien is a global healthcare products company and manufacturer of medical devices and supplies. Following a series of acquisitions over the last two decades, Covidien has emerged one of the largest medical device manufacturers in the world.

5. Covidien specializes in cardiovascular products and services. Among the medical devices that Covidien sells are devices designed to treat a variety of vascular conditions, such as stents (which keep arteries open), catheters (which allow passage through blood vessels), atherectomy devices (called "cutters," which excise harmful plaques sometimes found in arteries), and radio frequency coils (which cauterize veins).

6. Covidien products are used in a variety of clinical settings, including doctors' offices, outpatient clinics and hospitals. However, while most companies specialize in either cardiovascular, endo-arterial products or venous products, Covidien has products to treat heart, vein, and arterial conditions. Covidien devices include endo-arterial products used in surgery (such as stents), as well as its "VNUS" product line, which can be used to treat common conditions such as varicose veins. Consequently, Covidien markets its products to the vascular specialists who perform procedures on both the "vein" and "artery" side of the business.

7. Because vascular conditions tend to disproportionately affect the elderly, many patients rely on federal government healthcare programs such as Medicare and Medicaid to pay for the treatment. Federal law is designed to ensure that healthcare decisions are not unduly influenced by financial gain to protect the integrity of federal benefits programs. For example, physicians are prohibited under federal law from taking compensation from device manufacturers in exchange for referrals to their practice or the preferential use of their products.

8. Despite this, Covidien has engaged in unlawful kickback schemes involving a network of physicians who are provided inducements such as cash payments, free advertising, free dedicated staff, discounted products and services, and referrals to their practices in exchange for their preferential use of Covidien's medical devices. The compensation offered and paid to physicians by Covidien included (1) compensation paid to physicians, either as advertising, honoraria, or fees, that was greater than fair market value; (2) sham payments for "trainings" that the physicians did not give; (3) below market value leasing agreements for venous catheterization equipment; and (4) free and discounted marketing staff. *See* Exhibit A (Endovenous Preceptorship Registration Form).

9. Covidien's violations of the law generally fall into two categories, which track the manner in which its "VNUS" and endo-arterial products are marketed, sold, and used by physicians. To increase sales and develop "brand loyalty" among physicians on the "vein side" of the business, Covidien engages in a nationwide scheme to sell its VNUS product line (for example, the radio frequency catheter) to physicians in exchange for illegal kickbacks.

10. Covidien sometimes attempted to conceal its practice of providing unlawful kickbacks through the use of temporary employees it called "per diem" employees. Though typically employed by temporary staffing agencies operating under contract with Covidien, "Per Diems" in fact work under the joint direction of Covidien sales representatives across the United States and the doctors to whom they are assigned. In a standard arrangement, one or more Covidien sales representatives are assigned a "Per Diem" to "cover" a physician with a high-volume practice in a particular region, and it is the Per Diem's primary responsibility to market the physician's practice. *See* Exhibit B (Per Diem Agreement). The goal of the Per Diem's relationship with the physician was to increase the number of patient procedures being performed by the physician, and in turn to increase the sale and use of Covidien products by that physician. *See* Exhibit C (Covidien Territory Business Plan). Though the Per Diem's job duties included only marketing on behalf of a particular physician, Covidien sometimes paid all the Per Diem's salary, or split the cost with the physician.

11. In addition to the free marketing, physicians are given sham payments for "trainings," and are provided Covidien products at below-market cost, all in exchange for the physician's agreement to use Covidien products on an exclusive or near-exclusive basis.

12. Covidien also acts unlawfully on the "arterial side" of its business. Covidien's endo-arterial products are marketed for off-label use by a network of Covidien's employees, who encourage and oversee the improper and illegal use of their products on patients.

13. The Food and Drug Administration ("FDA") regulates the manner in which medical devices may be used, including devices used in the treatment of arterial conditions. In service of its relationships with these physicians, however, Covidien actively promoted its endo-arterial products to physicians for off-label use, and trained its employees to promote and facilitate such unlawful conduct. For example, since at least 2008, Covidien promoted use of its Balloon Expandable and Self-Expanding arterial stents (approved for use as biliary stents) for off-label use by physicians performing procedures for which such stents were both dangerous and unapproved. Then, Covidien promoted use of its cutters for off-label use in the stent, which offered physicians additional reimbursement from Medicare. In fact, one way in which Covidien

evaluated job performance was on the employee's ability to market and demonstrate off-label use of certain stents and filters well before such use was approved by the FDA.

14. As set forth below, Covidien's actions violate the FCA, the CFCA, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, and have led to violations of the "Stark Statute," 42 U.S.C. § 1395nn.

PARTIES

15. Qui Tam Plaintiff and Relator Erin Hayes is an individual over the age of eighteen and at all relevant times was a resident of Ventura, California. From October 2008 until February 2013, he was a Territory Sales Manager. In October 2008, Relator Hayes was hired by VNUS, to sell medical devices for vascular therapy. Covidien purchased VNUS in approximately 2008 and Hayes became a Covidien employee.

16. Qui Tam Plaintiff and Relator Richard Ponder is an individual over the age of eighteen and at all relevant times was a resident of Temecula, California. From January 2010, he was General Manager at EV3, a company purchased by Covidien in 2012. From May 2012 until April 2013 he was a Regional Sales Manager for Covidien.

17. Defendant Covidien, Inc. is the United States affiliate of Covidien Ltd., a foreign corporation incorporated in Dublin, Ireland. Covidien's United States headquarters is in Mansfield, Massachusetts and its principle place of business is in Massachusetts. According to Covidien's website, "Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in four segments," including medical devices. *See* http://investor.covidien.com/phoenix.zhtml?c=207592&p=irol-newsArticle&ID=1296588&highlight=) (last visited February 18, 2014).

JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. § 1367 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31

U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

19. This Court has personal jurisdiction and venue over the defendants pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the defendants have minimum contacts with the United States.

20. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because Covidien can be found in and transacts or has transacted business in this District.

STATUTORY AND REGULATORY BACKGROUND GOVERNING COVIDIEN'S UNLAWFUL CONDUCT

Federal Government Health Programs

21. The federal, state and local Governments, through their Medicaid, Medicare, and other Government healthcare payors, are among the purchasers of Covidien products.

22. Medicare is a federal Government health program primarily benefiting the elderly. Congress created Medicare in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS").

23. Congress also created Medicaid in 1965 when Title XIX was added to the Social Security Act. Medicaid is a public health insurance program that provides health care services to low-income individuals, including families with children, seniors, persons with disabilities, foster care, pregnant women, and low-income people with specific diseases such as tuberculosis, breast cancer or HIV/AIDS. Medi-Cal is California's Medicaid program, and is financed equally by the State and federal government. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, except that Medicaid usually provides more expansive coverage than does Medicare.

24. Healthcare providers who meet the requirements for participation in the Medicare program are paid for healthcare services furnished to Medicare patients, provided that the services are reasonable and necessary for the treatment of the patient. Healthcare providers billing Medicare are required to enter into a contract with the federal government certifying their understanding that "no payment may be made…for any expenses incurred for items or

services...which...are not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395Y(a)(l)(A).

The False Claims Act and the Anti-Kickback Statute

25. The FCA was originally enacted in 1863 in response to concerns of fraud on the government during the Civil War. It was substantially amended in 1986 by the False Claims Amendments Act, Pub. L. 99-562, 100 Stat. 3153. The amendments were intended to create incentives for individuals with knowledge of government fraud to disclose the information.

26. The FCA provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 up to $11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government. 31 U.S.C. § 3729(a)(1)(A)&(B).

27. The California False Claims Act was enacted in 1987 as a companion to the FCA. The CFCA was the first State law of its kind, and largely tracks the provisions of the FCA. In 2012, the CFCA was amended (Assembly Bill 2492) to further conform the CFCA to the requirements of the FCA and to provide additional protections to whistleblowers who report on government fraud.

28. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which also applies to the state Medicaid programs, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by fines of up to $25,000 and imprisonment for up to 5 years.

29. The Balanced Budget Act of 1997 amended the Medicare Anti-Kickback Statute to include administrative civil penalties of $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. See 42 U.S.C. § 1320a-7a(a).

30. The California counterpart to the federal Anti-Kickback Statute is Welfare and Institutions Code § 14107.2. It prohibits any person from soliciting or receiving any remuneration "[i]n return for the referral, or promised referral, of any individual to a person for the furnishing or arranging for the furnishing of any service or merchandise for which payment may be made" or "[i]n return for the purchasing, leasing, ordering, or arranging for or recommending the purchasing, leasing, or ordering of any goods, facility, service or merchandise for which payment may be made, in whole or in part."

31. Health care providers who participate in the Medicare program are statutorily required to "assure" that their services are "provided economically and only when, and to the extent, medically necessary." 42 C.F.R. § 1004.10. Kickbacks increase Government-funded health benefit program expenses by inducing medically unnecessary treatment and excessive reimbursements. Kickbacks also reduce a patient's healthcare choices; physicians with a financial incentive to use particular products in turn limit their selection of products available to their patients, though less expensive or more efficacious products may be available.

32. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit providers from receiving remuneration paid with the intent to induce referrals, or business orders, including the use of medical devices, where the costs of equipment and products are determined as a result of the volume or value of any referrals or business generated. See 42 C.F.R. § 1001.952(f). Such remunerations are kickbacks when paid to induce or reward physicians' use of a medical device, product, or prescription medication.

33. The Medicare Anti-Kickback Statute contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protects Covidien's conduct in this case.

34. In 2010, the Affordable Care Act ("ACA"), Public Law No. 111-148, Sec. 6402(g), amended the Medicare Anti-Kickback Statute or Social Security Act, 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the

False Claims Act. A violation of the Anti-Kickback Statute now serves a predicate for a violation of the FCA.

35. The ACA also amended the Social Security Act's "intent requirement" to make clear that violations of the Social Security Act's anti-kickback provisions, like violations of the False Claims Act, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." 42 U.S.C. § 1320a-7b(h).

FDA Regulations

36. The Food and Drug Administration regulates medical devices based on the "intended uses" for such products. Before marketing and selling a medical device, a manufacturer must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. § 353(a).

37. The FDA reviews device manufacturers' applications for new devices to determine whether the device's intended uses are safe and effective. *See* 21 U.S.C. § 360c. In accordance with the FDCA, the FDA places all medical devices into one of three regulatory classes based on the level of control necessary to ensure safety and effectiveness of the device. According to the FDA, "classification is risk based [on]…the risk the device poses to the patient and/or the user is a major factor in determining the class to which it is assigned."

38. The FDA prohibits device manufacturers from marketing or promoting devices for uses not approved by the FDA. In general, an unapproved medical device may be used only on human subjects when the device is under clinical investigation and when used by investigators participating in a clinical trial. As described above, "off-label" refers to the marketing of an FDA-approved medical device for uses that have not undergone FDA review and approval.

39. While purely scientific or educational programs are permissible, sales and marketing presentations, promotions, or marketing to physicians for uses other than those approved by the FDA are considered off-label marketing or "misbranding" proscribed by the FDA. See 21 U.S.C. §§ 352(q)-(v). Additional proscribed marketing activity includes any attempts by a medical device sales representative to solicit discussions with physicians concerning off-label use. 21 U.S.C. § 331.

40. Strong policy reasons exist for strict regulation of off-label marketing. Off-label promotion bypasses the FDA's strict review and approval process and removes the incentive to obtain definitive clinical study data showing the efficacy and safety of a product.

41. The Department of Justice and the courts have recognized that a manufacturer's promotion of medical devices for off-label purposes is tantamount to an illegal inducement to physicians to submit fraudulent claims to the government for reimbursement. Because the False Claims Act explicitly holds liable a party that causes another to submit a fraudulent claim, off-label promotion of medical devices are actionable under the FCA. 31 U.S.C. 3729(a)(1)(A).

COVIDIEN'S PRACTICE OF UNLAWFUL KICKBACKS

42. Under the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any medical device for which payment is sought from any federally-funded health care program, including Medicare, Medicaid, and TRICARE, CHAMPVA, and others.

43. The Anti-Kickback Act is designed to, inter alia, ensure that patient care will not be improperly influenced by inappropriate compensation from the medical device industry.

44. Every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of health care services in the United States.

45. Despite this, Covidien has engaged in a nationwide practice of unlawfully compensating physicians in exchange for the physicians' exclusive – or near exclusive – use of Covidien products. Unlawful remuneration occurred in a variety of ways.

46. Like most device manufacturers, Covidien employs sales representatives assigned to regional territories around the United States. Each sales representative would be responsible for marketing and selling Covidien products to the vascular specialists within each territory. Covidien's sales representatives specialize in either venous or endo-arterial products.

47. Relator Hayes, for example, specialized in Covidien's VNUS product line. He was assigned the territory covering the greater Los Angeles area, which included cities from northern Los Angeles County, east to Bakersfield, and as far north on the coast to San Luis Obispo. Each

sales territory was typically comprised of approximately 50 "call points," which is the term used to describe individual physicians' practices.

48. Beginning in approximately 2010, and continuing through at least December 2013, Covidien utilized a large contingent of individuals employed by temporary staffing agencies to assist its regional sales representatives. Covidien refers to these workers as "Per Diems." Relator Hayes was one of approximately seven Territory Sales Managers in California, and was the only one of Covidien's California Territory Representatives who was not assigned a Per Diem.

49. In California and elsewhere, these employees are hired under a contract with Kelly Services, Inc., though on information and belief, Relators allege that other local staffing agencies are used in other parts of the country. *See* Exhibit B.

50. The assistance provided by "Per Diems" was simple. It consisted of marketing the practices of those physicians who are the highest users of Covidien devices. *See* Exhibit B, C. Per Diems directly and indirectly offered and provided remuneration to physicians in the form of free advertising, practice-specific marketing and screening, and sham payments for "training" that never occurred. At times, Covidien would "bill" physicians for marketing services, such as the design of advertisements, but then never collect for the work performed by the Covidien employees. *Id.*

51. To avoid disclosure of the true purpose of the Per Diem employees, Covidien participated in a scheme to conceal its unlawful conduct by paying for services and other items of value through payments made to Per Diems that are, in effect, salaries and/reimbursements to the physicians.

52. For example, Dr. C. Shawn Skillern, M.D., is a vascular surgeon who operates three separate offices under his umbrella practice called "West Coast Vascular." The offices are located in Ventura, Santa Barbara, and Thousand Oaks, California. Dr. Skillern is Covidien's largest "account" in the United States.

53. One of Covidien's divisions, "EV3," sells medical devices designed to assist with vascular therapy and treat PAD and varicose veins. EV3 has designated training centers where

physicians can attend seminars and learn about the diagnosis and treatment of vascular therapy, at a cost of approximately $3,000.

54. Covidien's second largest EV3 training center is located in Ventura County at Dr. Skillern's Santa Barbara office.

55. Dr. Skillern's high-volume use of Covidien products created incentives for Covidien to maintain and promote his practice. This was especially true because Dr. Skillern's practice began an expansion into arterial procedures in addition to his primary practice, which involved venous procedures. One way it did so was by paying for an $8,000 ad in the Santa Barbara News Press in June 2013. See Exhibit D.

56. On or about July 9, 2012, Relator Hayes attended a meeting organized by Covidien officials, which included Dr. Skillern and several Covidien employees, including Mark Andrew (Covidien's EV3 West Coast Regional Manager), Jason Charron (EV3 Territory Sales Manager), and Charlie Lechner (VNUS West Coast Regional Manager). The meeting was organized to discuss the manner in which Covidien could assist Dr. Skillern in generating more business through "vein screenings."

57. Dr. Skillern and other vascular surgeons attempt to obtain new patients by offering "vein screenings" in public places. A vein screening is a process designed to search for peripheral artery disease (PAD) and varicose veins. Participating physicians advertise in local newspapers that they will provide free vein screenings as a way to obtain new patients. Not surprisingly, physicians who utilize vein screenings to find new patients often diagnose patients with a condition called "vein reflux," an umbrella term used to describe a circulatory insufficiency in the veins of the lower extremity. It involves blood returning "backward" through venous valves rather than being pumped toward the heart for oxygenation. Vein reflux can be treated by vascular specialists employing medical procedures that require devices made by manufacturers such as Covidien. Diagnosis is made through the use of ultrasound technology at vein screenings.

58. During the July 9 meeting, Dr. Skillern requested that Covidien pay for his advertising for the vein screening, and threatened that he would discontinue use of Covidien medical devices and switch to a competitor.

59. Although Covidien's employees and Dr. Skillern knew that it was illegal for Covidien to pay for a physician's advertising, Mark Andrew, Covidien's EV3 West Coast Regional Manager, offered to launder the cost of Dr. Skillern's advertising for the vein screening by "using training dollars." Andrew explained that Covidien would compensate Dr. Skillern by sending him checks for fictitious training sessions at the EV3 facility of physicians allegedly referred by Covidien. Andrew stated that he would complete training request forms for physicians to be sent to Dr. Skillern's facility without actually sending any physicians to Dr. Skillern for training. Andrew also stated that he would send three checks for $3,000 each to Dr. Skillern for services never performed.

60. To ensure Dr. Skillern continued to use Covidien products, Covidien agreed to pay for the direct marketing of the West Coast Vascular practice.

61. Covidien also created sham "trainings" for Dr. Skillern to lead, but which are actually fabricated to conceal the payment for the free advertising. As part of the scheme hatched at the July 2012 meeting, for example, Mark Andrew approved payments from Covidien to Dr. Skillern for trainings that Covidien knew would not take place. Relator Hayes was charged with obtaining information from the newspaper regarding the process for advertising for Dr. Skillern. *See* Exhibit D. Mr. Andrew knew that no doctors would attend the trainings, and that Dr. Skillern would not need to attend them, which he did not. Despite this, Dr. Skillern ultimately received payments from Covidien worth $9,000. The advertisements ultimately ran three days per week, each week in June 2013. *See* Exhibit E.

62. Dr. Skillern and other physicians also benefitted from Covidien's practice of offering free use of the generators required for use of certain products through the use of "CAP Agreements." For example, Covidien catheters and radio frequency coils are used in an outpatient procedure called vein ablation, which relieves symptoms associated with varicose veins. Vein ablation works by sending bursts of radio frequency energy through a catheter (powered by a generator), heating up the wall of the vein until the varicose vein tissue is destroyed.

///

63. The catheter is heated by use of a generator that works only with Covidien products. Under the terms of these CAP agreements, Covidien would provide the providers with free use of the VNUS RFGPLUS Generator and/or the Covidien ClosureRFG™ Radiofrequency Generator (at a value of $35,000) in exchange for a commitment from the physician or the healthcare provider to purchase certain amounts of Covidien products. Federal law requires all such discounts to be in writing, and disclosed at the time of billing to federal health care programs. 42 CFR §1001.952(h). However, Covidien sales representatives routinely offered non-written discounts for volume sales of Covidien products, in violation of this regulation.

64. To hide these unwritten and undisclosed discounts, Covidien sales representatives submit paperwork internally to Covidien sales managers and are trained to characterize these requests as "trial" samples of Covidien devices for new customers. In fact, free samples of Covidien catheters and other devices are being provided to physicians who are existing – and usually high-volume – Covidien customers. Covidien did not track these products by batch number to ensure unwritten and undisclosed discounts are not being offered by its sales representatives.

65. Covidien knew or should have known that this conduct was unlawful and in violation of its own policy prohibiting the provision of services in order to eliminate a healthcare provider's overhead or other administrative business expense.

66. Covidien also pays for the marketing of specific physician practices by paying the salary of individuals who are actually in the employ of the physicians themselves. For example, Covidien paid, through an independent contractor relationship, individuals who worked for Dr. Donald W. Lee of Temecula, California. These individuals are, in fact, full-time employees of the physician who worked exclusively to market the physician's practice. However, they received either no compensation from the physician, or compensation at a rate reduced by the value of payments made by Covidien.

COVIDIEN'S OFF-LABEL MARKETING OF ARTERIAL PRODUCTS

67. Covidien endo-arterial products have been used off-label in the treatment of vascular conditions that involve "stenosis," or narrowing of the peripheral vessels from a buildup

of plaque. Plaque blockages can result in severe pain, limited physical mobility and non-healing leg ulcers. According to the American Heart Association, approximately 10 million people in the U.S. suffer from peripheral arterial disease, a condition in which harmful plaque builds up in the superficial femoral artery (SFA), the large artery that runs along the inside of the thighs. If plaque returns after it has been removed, the condition is called "restenosis."

68. When a PAD condition worsens, lesions can develop on the stenotic portion of the SFA, impeding blood flow, especially to the feet – a condition that can result in amputation. Physicians used to treat this condition by performing bypass surgery—i.e. bypassing the affected portion of the SFA by rerouting blood flow to the popliteal artery behind the knee.

69. Beginning in approximately 2004, atherectomy devices were introduced as the first non-surgical intervention to treat SFA stenosis. The atherectomy devices look like long, thin tubes, the head of which is a rotating blade that excises the plaque from inside the SFA as it is threaded into the affected portion of the vessel.

70. Beginning in approximately 2008, patients with acute stenosis in the SFA could not yet be treated on-label with a Covidien/EV3 stent, which remains in the body to keep the vessel open. At that time, Covidien had two products approved for use as biliary stents, a balloon-expandable (BE) stent and self-expanding (SE) stent. Biliary stents are used in the bile duct, frequently for patients with pancreatic cancer. However, the SE and BE stents were not approved by the FDA for use on the SFA until March 2012. *See* Exhibit F (available at http://www.businesswire.com/news/home/20120307006498/en/Covidien-Peripheral-Vascular-Stent-System-Receives-FDA#.UzXlL_ldXS4).

71. Despite the fact that the neither the SE nor the BE stent was approved for use on the SFA, Covidien sales managers and sales representatives were trained and expected to market the use of the stents for use in stenotic SFA patients. *See* Exhibits J-K.

72. As further progress was made in the industry for non-surgical interventions, Covidien compounded its unlawful promotion and marketing of products for off-label use. By 2004, Covidien's atherectomy device, the SilverHawk Peripheral Plaque Excision System, had been approved by the FDA only for "use in atherectomy of the peripheral vasculature." *See*

Exhibit H. According to the package insert for the SilverHawk, it "is specifically contraindicated…for in-stent restenosis at the peripheral vascular site." *See* Exhibits H-I (Silverhawk Plaque Excision System Instructions for Use; TurboHawk Peripheral Plaque Excision System Instructions for Use). The SilverHawk came in three sizes to allow it to be used in peripheral vessels of various sizes.

73. Despite this, sales representatives were trained to market the use of the SilverHawk—and a later model called the TurboHawk with the same contraindications—for use in in-stent restenosis. *See* Exhibit H-I. The off-label use of these cutters presented obvious risks to the patient. Dislodging plaque from the vessel can result in a fatal embolism. Covidien attempted to compensate the increased risk posed by the cutter in two ways: first, by instructing physicians to use the "medium"-sized model of the SilverHawk; and second, by using off-label another Covidien product, the Spider FX, a filter that was intended to prevent a thrombotic embolism by catching micro particulate debris.

74. For example, as early as 2009, Covidien sales representatives were judged on the basis of their ability to market the SilverHawk for off-label use. The PV Sales Territory Manager Performance Review 2009 judged "sales competencies" of Covidien sales representatives, including their ability to sell the SilverHawk. Among the categories on which they were judged was the ability to "target[] and develop[] 'Hawkers' at the rate of >1/year"; and their "ability to use SilverHawk to pull through Stent, PTA and Embollic Protection business." *See* Exhibit J.

75. In 2009, the SilverHawk was not approved for use on in-stent conditions, and Covidien sales representatives could not lawfully promote its off-label use for such conditions. Despite this, Covidien sales representatives would create PowerPoint marketing presentations in which they would detail the use of Covidien products for off-label use. In a typical presentation, the Covidien sales representative would provide examples of off-label use to physicians, guidance in a clinical setting, and explanations of the reimbursement rates physicians could expect for the off-label use of Covidien products.

76. For example, a March 2010 Covidien presentation describes the treatment of a 73-year old patient in Stockton, California with a range of vascular conditions and a history of

diabetes. The presentation describes the surgeon's use of the TurboHawk and a Spider FX filter "After Off- Label Product Discussion" with Covidien, and a "mild vessel spasm" treated with drugs after the procedure. *See* Exbibit G. By using the doctors' names in such marketing materials, Covidien hoped to create an influential list of opinion makers that would influence further off-label use by other physicians. Dozens of similar presentations were offered to vascular surgeons and cardiologists around the country, inducing physicians to submit false claims for treatment to Medicare.

77. In approximately January and February 2010, Relator Ponder attended two weeks of training at EV3 headquarters in Plymouth, Minnesota. Other Covidien managers were present. The training was designed to train territory managers in the use of the company's plaque excision devices and stent devices, and was conducted in Covidien's animal labs. Regional Managers and territory managers were expected to conclude the training session with a "certification" on use of tbe SilverHawk/TurboHawk, and specifically, on the in-stent restenosis procedure that had not yet been approved by the FDA. Covidien attempted to conceal its marketing efforts by characterizing off-label use as something the "physician chooses" to do. *See* Exhibit J.

78. Covidien's promotions of off-label use were facilitated by the trainings the company provided to its sales managers. In 2010, Mr. Andrew, the Western Regional Manager for EV3, the Covidien business unit in charge of the sale of the TurboHawk, sent an email to several managers on February 22, 2010 that explained how the Company had developed a way to use Spider FX filter "in-stent" – i.e., off-label – in conjunction with the TurboHawk, which was a problem discussed at the training in Plymouth, MN: "Folks, I have now informed you of the issue that was brought up today by marketing. They are going to change the hub. Unofficially it seems to work fine if you do this…The technique is to put the delivery catheter in about 3 inches and deploy the spider in the trailblazer and then push it through. It works and takes the hub out of the equation. If anyone has had an issue using this technique let me know right away." *See* Exhibit L.

79. Covidien's managers were expected by Covidien to promote and market the use of the SilverHawk for off-label use by, in turn, training their sales representatives in how to do so.

For example, sales representatives were given sales quotas for both plaque excision devices, as well as stents that could only be practically achieved by off-label use. Sales representatives who failed to meet these quotas were put on performance improvement plans that involved reiteration of Covidien's expectations that they would be able to convince physicians to use the TurboHawk off-label.

80. By 2012, at a national sales meeting in Las Vegas, sales representatives openly discussed the off-label marketing of Covidien's products. In the context of Covidien's acquisition of several different companies, Covidien's general counsel was invited to attend the meeting to offer guidance about compliance with FDA regulations prohibiting the promotion of off-label use of its products. However, rather than declaring the practice against company policy, Covidien's regional sales manager told the assembled group the conversation would need to be taken up "offline."

81. The resulting sales practices clearly involved off-label promotion of Covidien products. Internal Covidien training materials encouraged sales representatives to encourage physicians who were using its products on-label in patients with "above the knee" vascular conditions to extend their treatment to off-label use in patients with "below the knee" conditions. Sales representatives were trained to explain to physicians that higher "returns on investment" could be achieved through the use of the "Hawk" in both on- and off-label use.

82. Covidien sales representatives were actively promoting and marketing use of its biliary stents for use in the lower extremities—a use for which the product had not been approved. Covidien closely tracked, by physician and sales representative, the number of outpatient procedures for which its biliary stents were being used. Increasing sales associated for such procedures was the result of off-label use that its sales representatives were trained to market and promote.

83. Another way Covidien promoted the off-label use of its products was to offer physicians "rebate incentives" that created unambiguous financial incentives for using Covidien products off-label. For example, biliary stents can typically be placed only in more acute clinical

settings, such as hospitals. Because of the nature of the procedure, Covidien was aware that biliary stents could not be placed during outpatient procedures at a physician's office.

84. Covidien tracked the sales data by both Covidien employee and healthcare provider. Internal sales records show the sales numbers for Covidien's stents, which were being purchased for use in non-acute clinical settings such as doctor's offices and cardiac catheterization laboratories ("cath labs"). However, the approved use of these stents was incompatible with use in such locations, which Covidien executives knew; in fact, Covidien managers expected sales representatives to promote the use of its stents in such settings despite the patient risks it presented. Covidien's unlawful inducements to physicians lead to the off-label use of its products by physicians, who billed the government for procedures performed with Covidien products that were not approved for such use.

85. Covidien sales representatives also had contractual tools at their disposal to increase the physicians' financial incentives to use Covidien products, both on- and off-label. For example, Covidien offered physicians "exclusive" contracts, "80-20" contracts, and other similar deals in which the physician agreed to use Covidien products in their offices at certain rates or in certain volumes in exchange for price discounts.

86. Covidien has long been aware that physicians were using its atherectomy devices off-label for treatment of in-stent restenosis conditions. For example, the website www.CLIUniversity.com includes videos of physicians performing in-stent restenosis procedures with Covidien's TurboHawk device See http://www.cliuniversity.com/video/treatment-stent-restenosis-turbohawk-atherectomy (last visited February 12, 2014). Covidien sales representatives were also present for the off-label use of its devices in procedures they attended and assisted the physicians in performing.

87. Knowingly paying physicians to induce them to use on-label or off-label for individuals seeking reimbursement from a federal Government health program or causing others to do so, while certifying compliance with the Stark Statute (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates state and federal

False Claims Acts. The Stark Statute prohibits certain physician referrals of designated health services if the physician has a financial relationship with that entity.

88. It was not until March 7, 2012, that Covidien announced that its SE Stent had received FDA approval for use in the SFA. According to its press release, "the U.S. Food and Drug Administration (FDA) has approved the EverFlex™ Self-Expanding Peripheral Stent System for use in the superficial femoral artery (SFA) and/or the proximal popliteal artery (PPA). The EverFlex System, which has been approved for peripheral indication in international markets since 2006, is now available in the United States, including a 200 mm stent length."

89. There was a significant financial incentive for physicians to take the advice of Covidien's sales representatives and use the SilverHawk and Spider FX off-label, and it was more than enough to compensate for any additional risk posed by the procedure.

90. PAD conditions are typically treated in one of three clinical settings. Surgical intervention, such as bypass surgery, is the most serious and would be performed in a sterile environment like the operating room in a hospital. Minimally-invasive interventions, such as the insertion of a cardiac stent, can be done in a catheterization laboratory ("cath lab"), which is an examination room in a hospital or clinic with diagnostic imaging equipment. "Office-based procedures" are the least invasive treatments, and can be done in a doctor's office.

91. The financial incentive for physicians to perform interventions in their office is plain. While physicians may be reimbursed at a higher rate for more invasive procedures, they must pay for the use of a hospital, and the number of patients they can treat in a day is far smaller than the number of patients that can be treated in an office-based setting. Reimbursement rates for office-based procedures involving the placement of a stent in the SFA routinely exceed $20,000. On information and belief, Relators allege that Covidien's off-label promotion and marketing of its products resulted in millions of dollars in product sales, and the submission of false claims to the Government for tens of millions of dollars.

///

///

///

COVIDIEN'S RETALIATORY CONDUCT AND EFFORT TO COVER UP ITS UNLAWFUL CONDUCT

92. Covidien also violated the anti-retaliation provisions of the FCA when it terminated Relator Hayes from his employment in February 2013 and Relator Ponder in July 2013.

93. Relator Hayes was a decorated salesperson for Covidien and received positive performance reviews for his work. His accomplishments included the following: (a) Rookie of the Year, 2009; (b) President Club, 2009 and 2010; (c) Silver Pen Award for placing first in his training class; (d) Highest territory growth award for 2009; (e) Sales Advisory Board member; and (f) Field Trainer, 2011; (g) 5 40% club wins. Each of his yearly performance evaluations (2008-2009, 2010, 2011, and 2012) exceeded company expectations and year-over-year Relator Hayes received a merit-based salary increases. Relator Hayes met or surpassed his sales quota for 17 consecutive quarters and received salary increases based on merit throughout his employment.

94. In July 2012, Relator Hayes attended a meeting with Dr. Skillern, Mark Andrew, and other Covidien officials. In October 2012, one of the managers who attended the July 2012 meeting, Charlie Lechner, left Relator Hayes a voicemail informing him that "Mark Andrew said the monies will be there for the vein screening." Relator Hayes understood that Covidien was not allowed to provide free services in order to eliminate a physician or health care practitioner's overhead or other administrative business expense. Relator Hayes became extremely concerned that Covidien was engaged in a practice of unlawful conduct.

95. On or about November 14, 2012, Relator Hayes sent letters to the Federal Bureau of Investigation and U.S. Department of Health and Human Services describing Covidien's business practice of engaging in a kickback scheme to persuade physicians to purchase and use Covidien's products. Relator Hayes' correspondence stated that Covidien was violating laws governing the use and sale of medical devices, anti-kickback statutes, and the Stark Statute.

96. Relator Hayes' letters also detailed Covidien's business practice of sending "per diem" representatives to assist physicians in recruiting patients in exchange for the physicians' agreements to use Covidien medical devices exclusively, and not use medical devices and procedures manufactured or distributed by Covidien's competitors.

97. On January 30, 2013, Relator Hayes informed Doug Clark, Covidien's Vice President of Sales for the West Division, that he had sent letters to government agencies regarding what he believed to be Covidien's unfair and illegal business practices and kickback schemes. Clark recommended that Hayes speak with Covidien's Chief General Counsel of Compliance, Jeanne Hickey.

98. On February 4, 2013, Relator Hayes revealed to Hickey the contents of his letters to the FBI and DHS, including the details described above. Relator Hayes also explained that he was experiencing harassment in the workplace due to the release of his letters. General Counsel Hickey advised Hayes to "sit tight" and she would get back to him.

99. Hayes, after hearing nothing further, reached out to Hickey to set up a second conference call on February 11, 2013. Relator Hayes explained that he was still being barassed.

100. On February 15, 2013, Hayes participated in a conference call with Clark, Hickey, a Human Resources representative, and two other Covidien employees. Clark listened to Hayes' many concerns but nothing was resolved.

101. On February 20, 2013, Hayes felt severely ill and visited the emergency room where he was diagnosed with pneumonia and prescribed bed rest. Relator Hayes informed Clark that he would be unavailable to attend a meeting that same day in Bakersfield. Clark emailed Hayes stating that he was upset and concerned with Hayes' absence, berated Hayes and threatened him with corrective action, and demanded proof of the hospital visit. Relator Hayes promptly scanned Clark a copy of his admission bracelet and receipt from Simi Valley Hospital.

102. On February 25, 2013, on a call with Clark, Hickey, and a Human Relations representative, Covidien terminated Hayes' employment on trumped-up charges it described as a "lack of integrity." Relator Hayes was told that he had improperly sold Covidien devices to a physician who had offices in both his territory, and the territory of another Covidien sales representative. The allegations were false and without merit, and plainly a pretext for Relator Hayes engaging in whistleblowing activity protected under State and Federal law. Covidien had loose territory restrictions for its salespersons and had a stated business policy of "closing the

deal" instead of adhering to rigid territories. Hayes' last day of employment with Covidien was February 25, 2013.

103. Relator Ponder, who was Hayes' supervisor, was blamed for Relator Hayes' protected activity and terminated for supporting Hayes' decision to come forward with allegations of unlawful conduct. Relator Ponder's repeated support of Hayes during conference calls prior to and subsequent to Hayes' retaliatory termination made Relator Ponder the target of Covidien officials who believed that Relator Ponder was complicit in Relator Hayes' whistleblowing activities.

104. Because Relator Ponder supported Relator Hayes, he was fired in retaliation for Relator Hayes' conduct.

105. Since Hayes' termination, he has reasonably and diligently sought comparable employment. However, defendant has obstructed Hayes' efforts to obtain gainful employment. First, Covidien has published false statements about Hayes and has accused him of breaching his alleged duties of confidentiality and nondisclosure.

106. Second, Covidien obtained confidential correspondence between Relator Hayes and the Division of Occupational Safety and Health ("OSHA") in which he made confidential complaints about workplace safety and health hazards. Specifically, Relator Hayes reported observing illegal reprocessing of catheters by medical providers at their clinics where used and bloody VNUS catheters in cardboard boxes were stacked without required biohazard stickers, bags, or warnings. Covidien obtained these confidential OSHA reports and circulated them to the physicians named in the reports in order to damage Relator Hayes' continued ability to work in the industry.

107. Third, Covidien falsely accused Relator Hayes of harassing a medical assistant in Dr. Skillern's office by electronic mail.

108. Fourth, Covidien attempted to scapegoat Relator Ponder in an effort to insulate Covidien from any accusations of wrongdoing. Covidien created a pretext to terminate Relator Ponder for violating unwritten policies when in fact, Relator Ponder was merely terminated in retaliation for his support of Hayes.

109. These statements, individually and collectively, are defamatory, have damaged Relators Hayes and Ponder in the medical sales industry, and place them in a false light. As a result, Relator Hayes is essentially banished from obtaining comparable employment in the medical field and Relator Ponder has been unable to find comparable work in the sector.

HARM TO THE GOVERNMENT

110. As a result of Covidien's unlawful conduct, Covidien has caused the Government to pay for unnecessary medical procedures that were more expensive and therefore unreasonable. By creating improper and unlawful financial incentives for physicians to use Covidien products, and to use them in a manner not approved by the FDA, the Government has been subject to:

a. The submission of false and fraudulent claims to the Medicare and Medi-Cal programs seeking payments for services provided to patients;

b. The diminution of choice by the Government, resulting in an increase in the cost of medical goods and services provided to consumers.

111. Relators are informed and believe that Covidien's conduct is widespread and that, in the aggregate, results in additional costs to the Government of millions of dollars.

FIRST COUNT

Violation of False Claims Act, 31 U.S.C. § 3729 *et seq.*.

112. Relators re-allege and incorporate by reference the facts and allegations set forth in each of the preceding paragraphs as though fully set forth herein.

113. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

114. By virtue of the kickbacks, misrepresentations and submissions of nonreimbursable claims described above, Covidien knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim.

115. Through the acts described above, Covidien has knowingly failed to reimburse the Medicare, Medicaid, Tricare/Champus, and the Federal Employees Health Benefits Program for moneys wrongfully received.

///

116. As a result of these false claims, the United States has been damaged and continues to be damaged, in an amount to be determined.

117. The United States, unaware of the falsity or fraudulent nature of the claims that Covidien caused, paid for claims that otherwise would not have been allowed.

118. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

SECOND COUNT

Violation of California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*

119. Relators re-allege and incorporate by reference the facts and allegations set forth in each of the preceding paragraphs as though fully set forth herein.

120. Through the acts described above, Covidien knowingly presented, or caused to be presented, false claims for payment or approval to an officer or employee of the state or of a political subdivision thereof. By virtue of the kickbacks, misrepresentations and submissions of nonreimbursable claims described above, Defendants knowingly presented or caused to be presented to the California Medicaid Program (i.e., Medi-Cal) false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

121. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Covidien, paid for claims that otherwise would not have been allowed.

122. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

123. Through the acts described above, Covidien knowingly made, used, or caused to be made or used false records or statements to get a false claim paid or approved by the state or by a political subdivision.

124. Through the acts described above, Covidien conspired to defraud the state or any political subdivision by getting false claims allowed or paid by the state or by a political subdivision.

///

125. As a result of these false claims, the State of California has been damaged and continues to be damaged, in an amount to be determined at trial.

THIRD COUNT

Retaliation, 31 U.S.C. § 3730(h)

(On behalf of Relator Hayes)

126. Relators re-allege and incorporate by reference the facts and allegations set forth in each of the preceding paragraphs as though fully set forth herein.

127. Relator Hayes was terminated from his employment on February 26, 2013 due to his lawful conduct taken in furtherance of his whistleblowing conduct.

128. Relator Hayes alerted Covidien officials that he was aware of violations that constituted unlawful conduct and formed the basis of an action under the False Claims Act. In response to Relator Hayes' reporting, he was terminated.

129. Covidien's conduct in terminating Relator Hayes violated 31 U.S.C. § 3730(h) and damaged Relator Hayes.

130. As alleged above, each of Covidien's officers, agents and employees involved in the decision to terminate Relator Hayes assisted and/or conspired to violate 31 U.S.C. § 3730(h), making each subject to liability.

131. Relator Hayes is entitled to the relief provided by 31 U.S.C. § 3730(h), including damages in an amount to be determined at trial.

FOURTH COUNT

Retaliation, 31 U.S.C. § 3730(h)

(On behalf of Relator Ponder)

132. Relators re-allege and incorporate by reference the facts and allegations set forth in each of the preceding paragraphs as though fully set forth herein.

133. Relator Ponder was terminated from his employment on July 10, 2013 for supporting Hayes' decision to come forward with allegations of unlawful conduct.

134. Because Relator Ponder supported Relator Hayes, he was fired in retaliation for Relator Hayes' conduct.

135. Covidien's conduct in terminating Relator Ponder violated 31 U.S.C. § 3730(h) and damaged Relator Ponder.

136. As alleged above, each of Covidien's officers, agents and employees involved in the decision to terminate Relator Ponder assisted and/or conspired to violate 31 U.S.C. § 3730(h), making each subject to liability.

137. Relator Ponder is entitled to the relief provided by 31 U.S.C. § 3730(h), including damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Relators pray that the Court issue the following relief:

A. That Covidien cease and desist from violating 31 U.S.C. § 3279, *et seq.* and the California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*;

B. Temporary and permanent injunctive relief;

C. An award of compensatory damages in an amount to be determined at trial;

D. That Defendants disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

E. That Qui Tam Plaintiffs be awarded the maximum amount of the "relator's share" allowed pursuant to § 3730(d) of the False Claims Aet and the California False Claims Act;

F. Civil penalties;

G. Treble damages;

H. Prejudgment interest on all damages awarded;

I. An award of attorneys' fees and costs;

J. That Relator Hayes be awarded all the relief to which he is entitled pursuant to 31 U.S.C. § 3730(h), including personal injury damages for emotional and mental distress, two times his back pay, interest on his back pay, reinstatement of his prior position, attorneys' fees and costs, and such other relief as the Court deems appropriate;

K. That Relator Ponder be awarded all the relief to which he is entitled pursuant to 31 U.S.C. § 3730(h), including personal injury damages for emotional and mental distress, two times

his back pay, interest on his back pay, reinstatement of his prior position, attorneys' fees and costs, and such other relief as the Court deems appropriate; and

L. That the United States, the State of California, and Qui Tam Plaintiffs recover such other and further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Qui Tam Plaintiffs hereby demand a trial by jury.

Respectfully submitted,

Dated: April 1, 2014

CHAVEZ & GERTLER LLP
BROWN POORE LLP

By: _____
Mark A. Chavez
Attorneys for Qui Tam Plaintiffs

EXHIBIT A

COVIDIEN

Today's Date: / /
Form may be completed by TSM or Attendee

Endovenous Preceptorship Registration & Learning Objective Identification Form

Thank you for your interest in Covidien RF Ablation Preceptorship Program. Courses are hosted by selected physician faculty and are designed to maximize the power of peer-to-peer education. Each course is tailored to accommodate your learning objectives. Please take a moment to register by providing the following information. Completed form must be submitted at least two weeks prior to target training date to Wansri.Saechew@Covidien.com. You will be contacted within three business days to confirm your course attendance.

First Name: _____ **Last Name:** _____

Degree: ☐ M.D. ☐ D.O. ☐ Other: _____

Specialty: ☐ Vascular Surgery ☐ Interventional Cardiology ☐ Interventional Radiology

☐ General Surgery ☐ Other:_____

Practice Name: _____

City: _____ **State:** _____

Email Address: _____ **Phone Number:** _____

Assistant Name: _____

Assistant Email: _____ **Assistant Number:** _____

Covidien Sales Representative: _____

What target training date has been identified? (mm/dd/yyyy) / /

If no date has been identified please list three preferred date(s) for training:

1) / / 2) / / 3) / /

Has a training physician been identified? ☐ **YES** (complete next line) ☐ **NO** (PACE will contact you)

Physician: _____ **@ Location:** _____

What mode of transportation will you use?

☐ I will drive myself

☐ My Covidien representative will drive me

☐ I need an American Express Travel passcode to make my travel arrangements
(Completed W9 must be received before American Express Travel code can be given)

WANSRI SAECHEW
CLINICAL EDUCATION ASSOCIATE | PROFESSIONAL AFFAIRS AND CLINICAL EDUCATION (PACE)
COVIDIEN | VASCULAR THERAPIES
15 HAMPSHIRE DRIVE | MANSFIELD, MA 02048
508.452.1632 (OFFICE) | 774.284.7143 (MOBILE) | 508.261.6015 (FAX) | WANSRI.SAECHEW@COVIDIEN.COM

COVIDIEN

Today's Date: / /

Form may be completed by TSM or Attendee

Have you attended a past Covidien sponsored training event? If so what was the date and location?

☐ No ☐ Yes

(mm/dd/yyyy) / / City: _____ State: _____

What is your primary purpose in attending Covidien's Preceptorship Program?

☐ To determine if offering treatment of vein care is appropriate for my practice and determine which interventions/technology my practice should adopt

☐ To develop a new vein practice

☐ To expand our current treatment options for chronic venous insufficiency to include endovenous radiofrequency ablation

☐ To begin performing Endovenous Radiofrequency ablation, which is already offered by others in my practice

☐ Other _____

What would you say are your greatest learning needs concerning RF Ablation?

_____

Is there anything else we can do to increase your comfort level with plaque RF Ablation procedure either at this course or in the future?

_____

WANSRI SAECHEW
CLINICAL EDUCATION ASSOCIATE | PROFESSIONAL AFFAIRS AND CLINICAL EDUCATION (PACE)
COVIDIEN | VASCULAR THERAPIES
15 HAMPSHIRE DRIVE | MANSFIELD, MA 02048
508.452.1632 (OFFICE) | 774.284.7143 (MOBILE) | 508.261.6015 (FAX) | WANSRI.SAECHEW@COVIDIEN.COM

Form **W-9**
(Rev. October 2007)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Give form to the requester. Do not send to the IRS.

Print or type See Specific Instructions on page 2.

Name (as shown on your income tax return)

Business name, if different from above

Check appropriate box: ☐ Individual/Sole proprietor ☐ Corporation ☐ Partnership
☐ Limited liability company. Enter the tax classification (D=disregarded entity, C=corporation, P=partnership) ▸ ----------
☐ Other (see instructions) ____

Exempt payee

Address (number, street, and apt. or suite no.)

Requester's name and address (optional)

City, state, and ZIP code

List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on Line 1 to avoid backup withholding. For individuals, this is your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the Part I instructions on page 3. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN* on page 3.

Note. If the account is in more than one name, see the chart on page 4 for guidelines on whose number to enter.

Social security number

or

Employer identification number

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me), and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding, and
3. I am a U.S. citizen or other U.S. person (defined below).

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the Certification, but you must provide your correct TIN. See the instructions on page 4.

Sign Here Signature of U.S. person ▸ Date / /

EXHIBIT B

PER DIEM AGREEMENT

This Per Diem Agreement ("Agreement") is made effective as of _____ (the "Effective Date"), by and between _____, whose address is _____ ("Individual") and Tyco Healthcare Group LP d/b/a Covidien through its Vascular Therapies Division, a Delaware limited partnership with an address of 5799 Fontanoso Way, San Jose, CA 95138 ("Company").

1. **Services.** Company has retained Kelly Services to provide Individual to perform the following services at the direction of designated Company employee(s):

(a) **Technical Support.** Individual's duties shall include providing technical product support to Company's customers during venous vascular procedures where Company's products are used. **Under the terms of this Agreement, Individual shall not provide technical support services to a healthcare facility and/or physician that Individual is also employed by unless approved by the healthcare facility and/or physician. In addition, Individual may not support on behalf of Company during Individual's regularly scheduled hours of employment by the healthcare facility and/or physician.**

Is Individual a health care provider (HCP)*? ____ Yes ____ No

In Individual related to a healthcare provider (by blood or marriage)? ___ Yes ___ No

***HCP includes a physician, nurse or any individual who is involved in the use, prescription, purchase or recommendation of Company's products.**

(b) The above identified activities shall be referred to as "Services". Such Services shall be provided in accordance with the terms and conditions of this Agreement and in particular, the Code of Standards set forth in Exhibit A. All Services shall be at the request and/or approval of the following designated Company employee(s): _____. Company shall have no obligation to compensate Kelly Services for Services performed by Individual that were not requested and/or approved by designated Company employees. Company shall not be required to use any minimum amount of Individual's Services, and Individual shall not be required to make himself/herself available for any minimum amount of time.

(c) **Training Requirements. Note that Individual must comply with the following training requirements in order for Kelly Services to be compensated for Services rendered:**

(i) Individual must complete all on-line training (referred to as "ELM Training") before Individual may provide any technical support to Company's customers;

(ii) Individual must complete all required Company product training within thirty (30) days of signing this agreement;

(iii) Kelly Services will not be paid for Individual covering any cases before all training has been completed by Individual;

(iv) Company will reimburse Kelly for the amounts Kelly paid the Individual in wages to complete the ELM Training.

(d) **Driving.** The Individual shall be responsible for the use of any vehicle used by the Individual in connection with an assignment, except for his or her workers' compensation claims.

2. **HIPAA.** Individual acknowledges that in the course of performing the Services, Individual may have access to data about patients of Company's customers that is protected by various national and state laws, rules and regulations governing the confidentiality of such information including, including without limitation, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Individual agrees to comply with all applicable laws governing the confidentiality of such data. Specifically, Individual agrees to hold all Protected Health Information (as defined in 45 C.F.R. § 160.103) ("PHI"), including, without limitation, patient medical records, in the strictest confidence, not to remove any PHI from any customer facility, and not to disclose it to any third party for any reason without the prior written consent of Company.

3. **Compliance.** The parties hereto expressly acknowledge that the Medicare antifraud statute, 42 U.S.C. § 1320a-7b, prohibits "illegal remuneration" as defined therein, in connection with the provision of goods or services for

which payment is made in whole or in part under Medicare. It is the intention of the parties hereto that this Agreement shall in all respects comply with the "safe harbor" regulation associated with the Medicare antifraud statute as set forth in 42 CFR 1001.952(d) dealing with the arms'-length contracts for personal services. If any portion of this Agreement is found, by any court or agency with jurisdiction over the subject matter hereof, not to be in compliance, that portion of the Agreement shall be deemed to be retroactively amended and reformed as necessary to comply with the statute and the applicable "safe harbor," and the parties shall cooperate in taking whatever steps are necessary to ensure such compliance. Further, both parties understand and agree that this Agreement, and any consideration paid under it, is not contingent upon Individual's use of, or recommendation to use, any Company products.

4. **Non-Compete**. During the term of this Agreement, Individual agrees that he/she will not provide Services such as those described in Section 1 above, for or on behalf of any direct competitors of Company in the endovascular market. Violation of this Section is grounds for immediate termination of this Agreement by Company. A list of the Company's direct competitors is attached as Exhibit B.

5. **No Conflicts**. Individual represents and warrants to Company that it is not currently subject to a non-competition, confidentiality or other such agreement with another client or former employer which conflicts with this Agreement or prohibits Individual from being engaged by or performing the Services.

6. **Governing Law**. This Agreement shall be governed by the laws of the State of Minnesota, without regard to choice of law rules.

7. **Entire Agreement**. This Agreement may be executed in separate counterparts, and by facsimile, each of which will be deemed an original, and when executed separately or together, will constitute a single original instrument, effective in the same manner as if the parties had executed one and the same instrument. This Agreement may only be modified in a writing signed by both of the parties hereto.

IN WITNESS WHEREOF, the parties hereto have subscribed their names to this Agreement effective the day and year written above.

INDIVIDUAL

By: _____

Name: _____
Date Signed: _____

Tyco Healthcare Group LP dba Covidien through its Vascular Therapies Division

By: _____

Name: _____
Title: _____

Date Signed: _____

EXHIBIT A
CODE OF STANDARDS

Individual must:

(a) Adhere strictly to all laws and regulations, in particular those governing the practice of medicine and surgery, and "anti-kickback" laws. This rule has primacy over all others.

(b) Observe all aseptic techniques in accordance with the hospital's policy and procedure standards.

(c) When present in the angio suite, behave only as a technical expert in the function of the device in use and its methods of use.

(d) Ensure that all discussions concerning device operation and implant techniques are consistent with the Instructions for Use.

(e) Use only presentations and marketing materials that have been approved, in writing, by Company.

(f) Immediately report to the Company any complaints of which Individual becomes aware relating to any product manufactured or distributed by Company. Complaints include any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of any device. That is, it includes any failure of the product to perform as expected, **regardless of whether or not a patient was injured**. The "device" includes the packaging, labeling, and instructions for use. Contact numbers for the Company's Complaint handling department are:

Primary Contacts: Judith Shaw at 508-452-4151 or Lawrence Rock at 508-261-6625.

It is permissible for Individual to do the following:

(a) Verbally instruct the customer in the application of the Product(s) from a technical viewpoint.

(b) Discuss indications, contraindications, warnings, and precautions stated in the Instructions For Use.

(c) Answer technical questions directly or by quoting medical papers or quoting specific answers given by other physicians, provided that such answers do not involve the promotion of Company's products outside their indications for use.

Individual cannot, and under no circumstance shall:

(a) Perform any act of surgery or practice medicine.

(b) Enter the sterile field, which is considered the area immediately around the patient.

(c) Cut or penetrate tissue or activate any device that penetrates or causes penetration, cutting or occluding of tissue.

(d) Make any physical contact with the patient, or with an instrument touching a patient.

(e) Communicate directly with the patient unless the physician is present and has given prior consent.

(f) Promote any devices in a manner inconsistent with their indications, as described in the Instructions for Use.

(g) Promote the use of any investigational devices.

(h) Use any marketing materials (including but not limited to letters, brochures, or presentations) created by Individual, unless such materials are approved via Company's standard procedures for the approval of marketing literature.

(i) Use any unlawful inducement in order to sell, recommend or arrange the sale, of Company's products. Individual may not directly or indirectly, offer or solicit any kind of payments, gifts, or contributions for the purpose of obtaining, giving, keeping or rewarding business.

EXHIBIT B
DIRECT COMPETITORS

Endovascular market

1. Angiodynamics
2. Dornier
3. Vascular Solutions
4. Cool Touch
5. Sciton
6. Total Vein Systems

Trellis

1. EKOS
2. AngioJet – MedRad

Dialysis

1. Bard
2. AngioDynamics
3. Teleflex/Arow
4. MedComp

Compression

1. ARJO/Huntleigh
2. Medi
3. Jobst
4. Aircast

Physician Locator Invitation Form

ev3 Endovascular, Inc. ("ev3") has developed a new application for Peripheral Arterial Disease (P.A.D.) patients to locate a physician in their community through the use of ev3's website, www.ev3.net.

In order to qualify, physicians listed in our physician locator must have completed ev3 SilverHawk® or TurboHawk™ training and actively use either device. If you would like to be included on ev3's physician locator data base please complete and submit this Physician Locator Invitation Form.

Physician Name: _____
Clinic/Hospital: _____
Phone: _____
Address: _____
_____
Email (optional): _____
Web Address: _____
TM Name: _____

Does this physician meet the minimum case requirements? Yes: _____ No: _____

Does the physician have the resources to accommodate additional P.A.D. patients? Yes: _____ No: _____

By signing this form you are granting ev3 permission to post your information on the physician locator website. Patients looking for a physician in their area will be able to access your information.

Physician Signature: _____ Date: _____
TM Signature: _____ Date: _____

Note: ev3 reserves the right to remove your name and contact information from its physician locator at any time without notice.

Fax to: Dan Kuhl at 763 398-7200 or Email to Span@ev3.net

EXHIBIT C

Covidien Territory Business Plan

30 Day Plan:

- Gain the clinical and product knowledge needed to excel within the territory.
- Start contacting existing Covidien customer's and set a foundation with them; understand their ideas and continue to help grow their business.
- Work closely with the Territory Manager on new business strategies.
- Research and develop new relationships with customers to generate new business.
- Schedule introductory meetings with accounts to discuss the next steps for their business and understand their expectations.

60 Day Plan:

- Implement new strategies with customers.
- Educate myself on clinical procedures. Run and start managing clinical cases more proficiently with doctors and office staff.
- Set-up dinner and lunch meetings with doctors and/or office staff to collaborate and expand their business through referral marketing.
-

90 Day Plan:

- Develop and maintain key relationships with customers.
- Manage and arrange strategies in order to see measurable territory sales results.
- Start to capitalize on growth strategies through the rapports built with doctors/office staff.

EXHIBIT D

Hayes, Erin

From: Hayes, Erin
Sent: Saturday, August 25, 2012 6:18 PM
To: 'erinhayes1972@gmail.com'
Subject: FW: Santa Barbara News-Press

FYI

From: B Walker [mailto:bwalker@newspress.com]
Sent: Thursday, July 12, 2012 3:41 PM
To: Hayes, Erin
Subject: RE: Santa Barbara News-Press

Thanks for letting me know!

I'll be on the lookout for your email when you are ready to start.

Beverly Walker
Retail Advertising Consultant
Santa Barbara News Press
805.564.5221
805.564.5139-fax
bwalker@newspress.com

From: Hayes, Erin [mailto:Erin.Hayes@covidien.com]
Sent: Thursday, July 12, 2012 3:30 PM
To: B Walker
Subject: RE: Santa Barbara News-Press

Beverly, we will do this, trust me we will do this, we need to wait a week until Dr Skillern meets with Cottage hospital CEO, once that meeting has happened then we can move forward with the AD, thanks again for all your help, Erin

From: B Walker [mailto:bwalker@newspress.com]
Sent: Wednesday, July 11, 2012 2:43 PM

To: Hayes, Erin
Subject: RE: Santa Barbara News-Press

Good Afternoon Erin,

I spoke with my manager and this is what we have devised:

Quarter Page ad, full color, 2 days a week, 4 week run:

$1,846.82 for 2 ads per week
[Priced @ $25,000 contract rate-$26.14/per column inch X 31.5" = $823.41 + $150 color = $973.41 per ad]
4 week run
GRAND TOTAL: $7,787.28
Difference of $712.72

Best days would be Sunday and then Friday as readership goes up for weekend event/happenings and home delivery increases as readers buy the weekend bundle of papers- Fri, Sat & Sun. You were also interested in Thursday – again another very good day as Food section publishes that day which also increases readership.

Prepayment is required, please.

Please let me know if I can provide any further information or answer any other questions.

Hope you can join us!

Thank you!!!

Beverly Walker
Retail Advertising Consultant
Santa Barbara News Press
805.564.5221
805.564.5139-fax
bwalker@newspress.com

From: Hayes, Erin [mailto:Erin.Hayes@covidien.com]
Sent: Wednesday, July 11, 2012 1:55 PM
To: B Walker; Charron, Jason; Charron, Jason; Andrew, Mark; Lechner, Charlie
Subject: RE: Santa Barbara News-Press

Beverly,

I met with the doctor yesterday and we WILL go ahead with the ad, however, our budget is $8,500, what can you do with that? Here is what we need.....

1) Full Color
2) 3 Columns, (6.437" wide X 10.5" high)
3) Ran for 4 weeks
4) Best days to run each week

What can you do??? Trust me he will be a repeat customer and a great client for you, if you could work with us the best you can this first time, then trust me there will be repeat business. Once the AD proves itself which I know it will because I have done this many times before, the doctor will see the value and continue to advertise. I attached a copy of the AD, it's an example of what it will look like so you can get an idea of what we are trying to do.

Take Care,
Erin Hayes
805-990-8035

From: B Walker [mailto:bwalker@newspress.com]
Sent: Monday, July 09, 2012 3:44 PM
To: Hayes, Erin
Subject: Santa Barbara News-Press

Hi Aaron,

Thanks for your interest in the Santa Barbara News-Press.

Below is the info that we discussed on the phone.

Please let me know what your budget is and let me try and see what I can work out of you.

I am out of the office for the rest of the day. I will get back with you tomorrow.

You were inquiring about running a quarter page ad - 3 columns X 10.5" (6.437" wide X 10.5" high) on a Thursday and Sunday, full color. Here is the breakdown for those days at open rate-$35.33 per column inch, Color Charge $420 per ad, per day:
Thursday - $1532.90
Sunday - $1310.21
TOTAL: $2843.11 – per week
4 week total - $11,372.44

Here is another option to consider. We would offer you the discounted per column inch rate on our rate card of $28.26, color charge $277 per ad per day if you were to include Monday at a 50% discount, you would also get Tuesday for FREE, if you were to add Monday and Tuesday.

Thursday - $1167.19
Sunday - $989.15
Monday - $494.58 (50% discount)
Tuesday – FREE
TOTAL: $2,650.92 – per week
4 week total - $10,603.68

Prepayment is required. I've also attached our rate card so that you can see deadlines – to reserve space for Thursday; deadline is Monday @ 4:00pm.

Beverly Walker
Retail Advertising Consultant
Santa Barbara News Press
805.564.5221
805.564.5139-fax
bwalker@newspress.com

EXHIBIT E

Local SANTA BARBARA COUNTY NEWS

Sea lion mom and pup struggle to survive

We've seen many births at the Santa Barbara Marine Mammal Center. Sometimes we've pulled pups out when they were stuck and even performed Caesarean operations when things weren't going well.

Even so, none of this happens often because California sea lion pups normally are born on the Channel Islands.

It always comes down to the mothers. When they come to us, it's only because they're in trouble. In this case, the mom had been suffering from domoic acid poisoning. Without help, she would have died.

The first question always is, "Does the pup get domoic acid poisoning from its mother?"

Some pups are stillborn. Others last a few days, going through seizures despite the best treatment, then die. Others survive the seizures. Some show no symptoms at all.

This pup was born minutes after the waters broke. Natalie Nelson, a senior staff member, cut the umbilicus. The pup started squirming around, calling out and instinctively searching for a nipple. Its mother was exhausted, however, certainly understandable under the circumstances.

Nonetheless, the mother touched noses with the pup and they called back and forth to each other. We left them alone so they could bond if the mother was willing.

PACIFIC LOG

Peter Howorth

Some mothers are so sick that they immediately abandon their pups. Others may turn on them and try to kill them. If all goes well, though, the mother and pup will bond.

The next decision to make when confronted with such a situation is when or if intervention is necessary. Will the mother nurse the pup? Can she even do so? You can't leave things too long or the pup won't make it.

Although the birth went quickly and without complications, the placenta had yet to emerge. It finally did, but so far the mother had shown no signs of being willing to nurse the pup.

We administered a small amount of fluid to the pup and waited. Many hours later, with the pup still squalling for food, we administered some of our specially designed formula. The pup, content at last, went to sleep. The immediate crisis was over.

Over the days that followed, the mother finally started lactating and the pup was helped to the nipple. This lasted only a short time, so the pup was fed formula again.

Can the pup get domoic acid poisoning from the mother's milk?

We've had mothers poisoned by domoic acid nurse their pups without ill effects. Moreover, the mother's milk can help boost resistance to various diseases. When we can, we prefer to allow the mothers to nurse their pups.

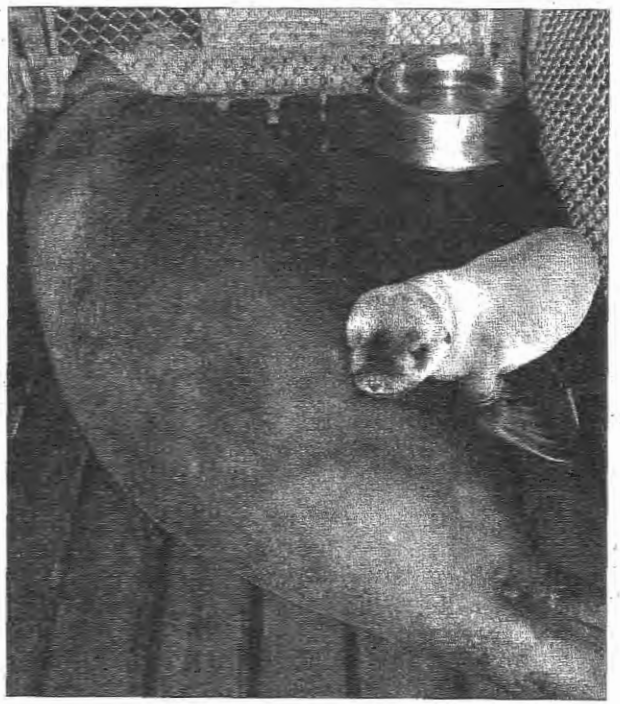
This entire process is a delicate balancing act of constantly assessing the health of both the mother and pup and making several decisions every day as to what is best.

The longer the pup survives without complications, the better the chances of its ultimate survival. If it remains active and vocal, if it gains weight, if it presents no adverse symptoms, its chances improve daily.

As to the mother, once she has her pup, her chances improve dramatically. The next hurdle is whether or not the mother will start to eat. Normally, the mothers do not leave the pups and seek food until eight days after the pup is born.

So much of helping wild animals gets down to understanding their natural history, their health problems and knowing just what to do and when to do it.

Peter Howorth has followed the sea for more than 50 years, first as a competitive free diver, surfer and professional diver. He captured marine mammals for sea life parks in the 1960s and founded the nonprofit Santa Barbara Marine Mammal Center in 1976. He serves as an environmental consultant for offshore projects, helping to prevent impacts to marine life. He has authored books and has been a columnist for the News-Press for more than 25 years. Any opinions are his and not necessarily the newspaper's.



PETER HOWORTH

This California sea lion pup was born just over a week ago at the Santa Barbara Marine Mammal Center. Its mother was suffering from domoic acid poisoning.

EXHIBIT F

Business Wire
A Berkshire Hathaway Company

COVIDIEN

Covidien Peripheral Vascular Stent System Receives FDA Approval

EverFlex™ Self-Expanding Stent Approved for Superficial Femoral and Proximal Popliteal Artery

March 07, 2012 04:05 PM Eastern Standard Time

MANSFIELD, Mass.–(BUSINESS WIRE)–Covidien (NYSE: COV), a leading global provider of healthcare products, today announced that the U.S. Food and Drug Administration (FDA) has approved the EverFlex™ Self-Expanding Peripheral Stent System for use in the superficial femoral artery (SFA) and/or the proximal popliteal artery (PPA). The EverFlex System, which has been approved for peripheral indication in international markets since 2006, is now available in the United States, including a 200 mm stent length.

> "Having an indication in the SFA - as well as a 200 mm stent - is imperative when treating Peripheral Arterial Disease (P.A.D.)."

The clinical data supporting the FDA approval of the EverFlex System for use in the peripheral vasculature was obtained through the DURABILITY II Investigational Device Exemption trial that enrolled patients at clinical sites within the U.S. and Europe. DURABILITY II is the first clinical study to evaluate lesions up to 18 cm and to specifically test the performance of a single long, up to 200 mm stent, in the SFA and PPA. Specifically, the study results show no major adverse events at 30 days and a low one-year stent fracture rate of 0.4 percent. Additionally, primary patency at one year was 67.7 percent when analyzed by simple proportions of patients patent; using Kaplan-Meier time-to-event analysis, it was 77.2 percent.

"DURABILITY II is a landmark trial intended to study the patency and fracture resistance of placing a single nitinol stent in the superficial femoral artery. It provided the clinical evidence necessary to demonstrate that you can successfully treat long, complex lesions in the SFA with the EverFlex Self-Expanding Peripheral Stent," said Dr. Krishna Rocha-Singh, MD, Director, Prairie Vascular Institute, Springfield, Illinois, and co-national principal investigator of DURABILITY II.

Until now, physicians often addressed longer lesions by overlapping multiple stents. Overlapping stents have a higher propensity to fracture, thereby increasing the potential for restenosis to occur. Being able to place one long stent, versus multiple shorter stents, may lead to better long term clinical performance.

"The DURABILITY II findings demonstrate the safety and effectiveness of our EverFlex stents," said Mark A. Turco, MD, Chief Medical Officer, Vascular Therapies, Covidien. "Having an indication in the SFA - as well as a 200 mm stent - is imperative when treating Peripheral Arterial Disease (P.A.D.)."

One of the most common vascular diseases, P.A.D. occurs when leg arteries become narrowed or blocked by plaque. These blockages can result in severe pain, limited physical mobility and non-healing leg ulcers. According to the American Heart Association, approximately 10 million people in the U.S. suffer from P.A.D.

ABOUT COVIDIEN

Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2011 revenue of $11.6 billion, Covidien has 41,000 employees worldwide in more than 65 countries, and its products are sold in over 140 countries. Please visit www.covidien.com to learn more about our business.

Photos/Multimedia Gallery Available: http://www.businesswire.com/cgi-bin/mmg.cgi?eid=50196216&lang=en

Contacts

Vascular Therapies
Rachel Bloom-Baglin, 508-261-6651
Vice President, Communications
rachel.bloombaglin@covidien.com
or
Bruce Farmer, 508-452-4372
Vice President
Public Relations
bruce.farmer@covidien.com
or
Cole Lannum, CFA, 508-452-4343
Vice President
Investor Relations

cole.lannum@covidien.com
or
Todd Carpenter, 508-452-4363
Director
Investor Relations
todd.carpenter@covidien.com

The FDA has approved Covidien's EverFlex™ Self-Expanding Peripheral Stent System and is now available in the United States - including a 200 mm stent length. (Photo: Business Wire)

EXHIBIT G

Dr. Jim Morrisey
St. Joseph's Hospital Stockton, CA.
March 8, 2010

Patient Information & Procedure Overview

Patient:

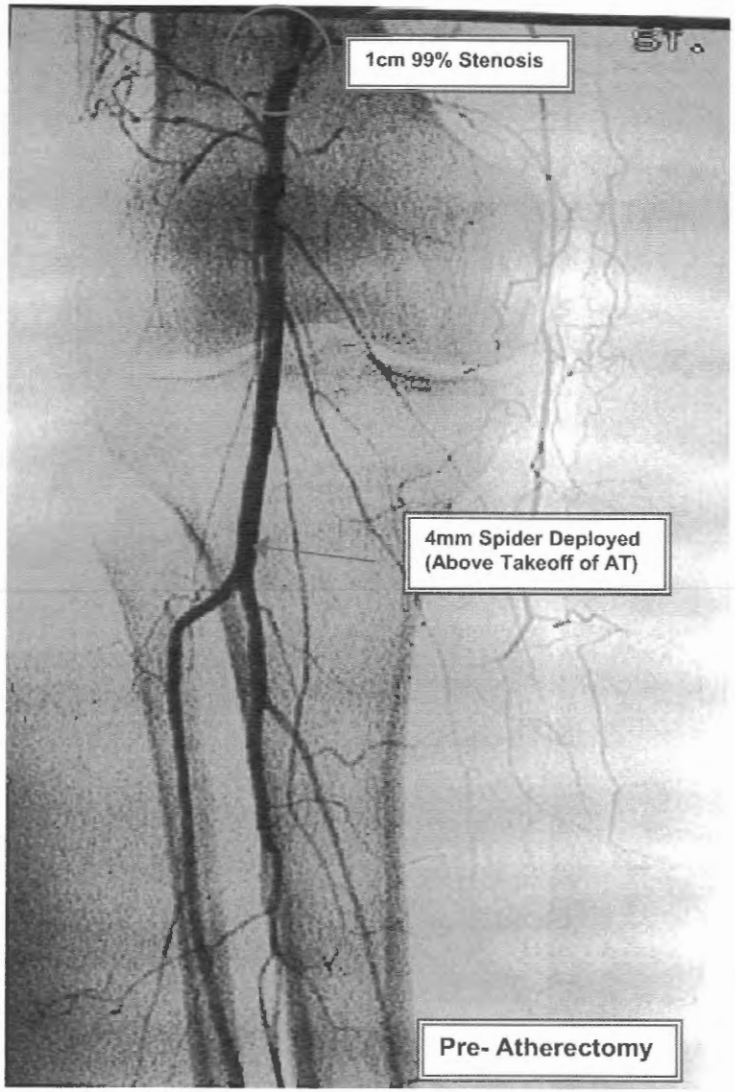
- 73 y.o. female with complaint of ≤30 yd. Claudication in Rt. Leg. Rt. Leg ABI = 0.25; Lt. Leg ABI = 1.0
- History of Dyslipidemia, Hypertension, CAD and 24 year long Diabetes Mellitus II.

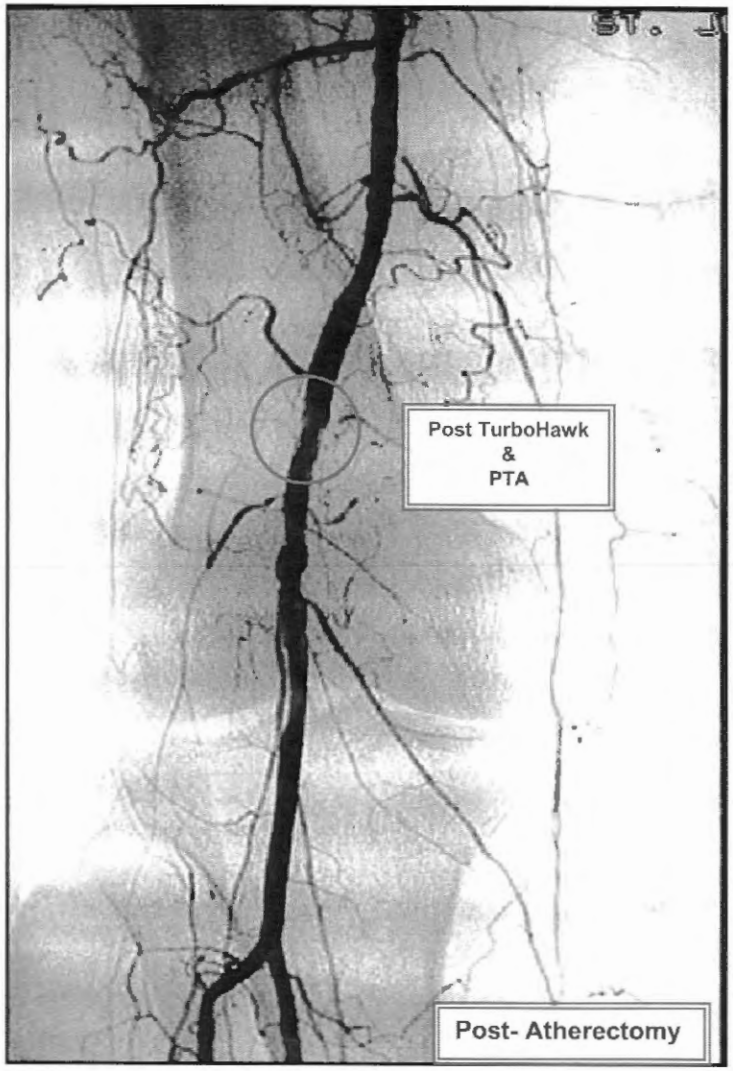
Procedure:

- Arterial Access Via Lt. Groin Contralateral to Rt. Leg
- 7F X 45cm Destination Inserted Over Stiff Angled Exchange Length Glidewire
- Stiff Angled Glide Crossed an app. 1cm 99% Calcified Stenosis in the Popliteal
- After Off- Label Product Discussion, 4mm Spider FX Deployed Thru GlideCath Superior to AT
- TurboHawk LS-C inserted; 8 Passes, Nosecone full
- Mild Vessel Spasm Post TurboHawk; Treated With 700mcg of Nitro Injected Thru Sheath
- Lesion Location Post Dil'd with an Evercross 5mm X 80mm Balloon

TURBOHAWK™

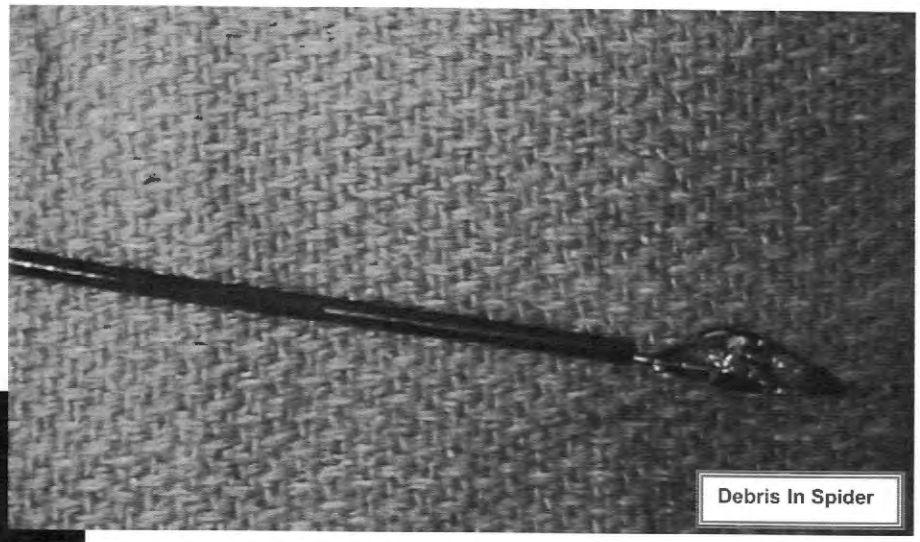
Dr. Jim Morrisey
St. Joseph's Hospital Stockton, CA.
March 1, 2010



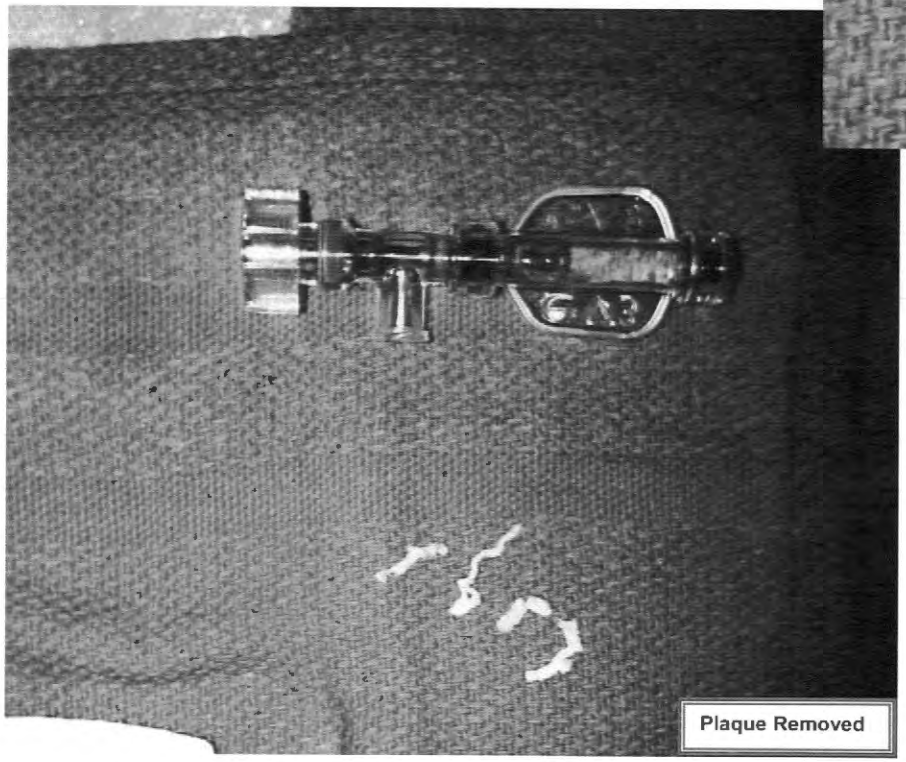


TURBOHAWK™

Dr. Jim Morrisey
St. Joseph's Hospital Stockton, CA.
March 1, 2010



Debris In Spider



Plaque Removed

EXHIBIT H

SILVERHAWK®
Plaque Excision System

INSTRUCTIONS FOR USE

CAUTION
Federal (US) Law restricts this device to sale by or on the order of a physician.

Device Description

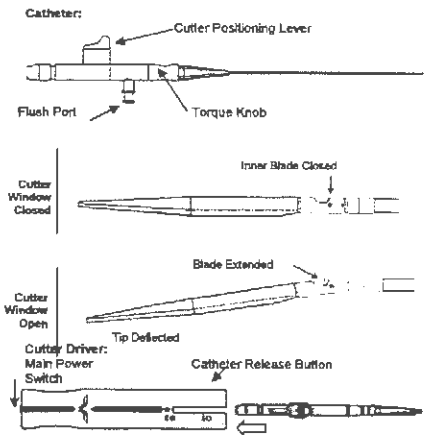
The SilverHawk® Peripheral Plaque Excision System and SilverHawk Cutter Driver are designed for the treatment of *de novo* and restenotic atherosclerotic lesions located in native peripheral arteries. The catheter consists of a flexible shaft designed to track over a 0.014" guidewire. At the distal end of the catheter is a small cutting assembly comprised of a rotating inner blade contained within a tubular housing. The proximal end of the catheter contains a connector and positioning lever designed to fit into a small, disposable, battery-driven Cutter Driver (provided separately), which powers the device.

When the catheter is connected to the Cutter Driver, retracting the positioning lever simultaneously turns on the motor and causes the distal portion of the cutter housing to deflect, forcing the device against the target lesion. At the same time, this motion exposes the inner rotating blade, preparing the device for lesion treatment. With the blade spinning, the catheter is slowly advanced across the lesion, "shaving" occlusive material from the artery. The excised tissue is captured and stored in the tip of the device. The cutting process is completed by advancing the positioning lever which brings the inner blade back into the housing, restoring the cutter to its "non-deflected" configuration, and automatically turns off the motor. This cutting sequence can be repeated as many times as necessary to achieve the desired degree of plaque excision.

Illustration and Nomenclature

Key Catheter Specifications

Catalog Number	P4056	P4052
Model	MSM (Violet)	LSM (Gray)
Usable Length	110cm	110 cm
Tip Length	6.0 cm	6.0 cm
Maximum Profile	0.105" (2.7 mm)	0.105" (2.7 mm)
Minimum Sheath Size	8F (2.7mm)	8F (2.7mm)
Shape Set	Mechanical	Mechanical
Maximum Guidewire Diameter	0.014" (0.36 mm)	0.014" (0.36 mm)
Minimum Vessel Diameter	3.5 mm	4.5 mm



NOTE: The Cutter Driver is protected against electrical shock (defibrillation proof – type CF) and against water (ordinary -type IPX0). Not suitable for use in the presence of a flammable anesthetic mixture. The SilverHawk Cutter Driver operates in a continuous mode and is internally powered by batteries.

Definition of Symbols

I	Main power ON	⊙	Secondary power ON
O	Main power OFF	O	Secondary power OFF

CF defibrillation proof applied part

Attention, consult accompanying documents

Catheter lock release

STERILE EO — **Sterilized with Ethylene Oxide gas.** Device is sterile if unit package is unopened and undamaged.

STERILE R — **Sterilized with Gamma irradiation.** Device is sterile if unit package is unopened and undamaged.

Intended Use/Indications

The SilverHawk Peripheral Plaque Excision System is intended for use in atherectomy of the peripheral vasculature. The catheter is NOT intended for use in the coronary or carotid vasculature.

Contraindications

- Any evidence or history of intracranial bleeding or aneurysm
- Any history of thrombotic or hemorrhagic stroke
- Known hypercoagulable state or coagulopathy or abnormal bleeding tendency
- Evidence of intraocular hemorrhage by opthalmoscopic exam
- History of thrombocytopenia or thrombocytosis
- Severe trauma, fracture, major surgery or biopsy of a parenchymal organ within the past 3 months
- Prolonged cardiopulmonary resuscitation
- Endoscopic peptic ulcer disease in the past 3 years or gastrointestinal bleeding within the past 3 months
- Genitourinary bleeding within the past 3 months
- Severe persistent hypertension (systolic pressure >180 mmHg)
- Allergy or intolerance to aspirin

Clinical Contraindications

The SilverHawk Peripheral Catheter System is specifically contraindicated:

- In the carotid artery; or
- In the iliac or renal vasculature; or
- for in-stent restenosis at the peripheral vascular site.

Restrictions

- Federal (U.S.A) Law restricts this device to sale by or on the order of a physician.
- This device is intended for single use only. Do not resterilize and/or reuse this device.

Warnings

Always use direct fluoroscopic observation when manipulating the SilverHawk Peripheral Catheter in the peripheral vessels. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Never advance the distal tip of the catheter near the floppy end of the guidewire. A catheter advanced to this position may not follow the guidewire when it is retracted and cause the guidewire to buckle into a loop. If this occurs, catheter and guidewire should be removed together to prevent potential damage to vessel walls. If resistance is still felt, the sheath should also be removed as part of the unit.

Avoid excessive movement of the SilverHawk Peripheral Catheter within the vessel at all times as doing so could result in embolization or vessel damage. In addition, excessive catheter manipulation with the cutter window open could result in embolization of previously excised tissue fragments.

The SilverHawk Peripheral Plaque Excision may only be used with the SilverHawk Cutter Driver.

This device is not to be used in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants.

Precautions

The SilverHawk Peripheral Plaque Excision System should only be used by physicians trained in percutaneous peripheral interventional procedures.

Use of this device should be limited to hospitals where surgical support is readily available in the event of a serious complication.

Adverse Events

Potential adverse events associated with use of this device and other interventional catheters include, but are not limited to the following:

- Arterial perforation
- Arterial rupture
- Bleeding complications
- Arterial spasm
- Embolism and/or arterial thrombosis
- Death
- Arterial dissection
- Emergency or non-emergency arterial bypass surgery
- Entry site complications
- Hypotension
- Infection
- Ischemia
- Restenosis of the treated segment
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair

Iliac/Renal Vasculature Adverse Events

Field experience associated with use of this device in the iliac/renal vasculature are identified below:

- Arterial perforation
- Death
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair

How Supplied

The SilverHawk Peripheral Catheter and Cutter Driver are packaged and sterilized individually, but shipped in a single shelf carton. Both are intended for single patient use only.

Sterilization and Expiration Dating

The SilverHawk Peripheral Catheter is sterilized using ethylene oxide gas. The SilverHawk Cutter Driver is sterilized using gamma radiation. Both devices are STERILE if unit package is unopened and undamaged.

Both the Catheter and Cutter Driver are intended for single use only and should not be reused or resterilized. Use prior to the "Use by" date printed on the package labels.

Storage and Use Conditions

Store sterile packaged Catheters and Cutter Drivers in a cool dry place until ready to use. Do not expose to organic solvents, ionizing radiation, ultraviolet light or alcohol-based fluids.

Directions for Use

Inspection

1. Prior to use, carefully inspect the Catheter and Cutter Driver to verify that neither the sterile packaging nor the devices themselves have been damaged.
2. Connect the Catheter to the Cutter Driver by inserting the proximal end of the catheter into the motor. Ensure the cutter positioning lever aligns with the slot in the Cutter Driver. When fully inserted, the catheter connector will lock into the Cutter Driver. To remove the catheter from the Cutter Driver, depress the catheter lock release button and pull the catheter from the motor.

Note: To avoid accidental activation of the Cutter Driver, be sure the cutter positioning lever is in the fully forward position prior to insertion into the Cutter Driver.

3. To confirm functionality of the catheter, advance and retract the cutter positioning lever. Ensure that the motor turns on and off automatically and that the inner blade moves freely. The catheter tip should deflect and return to its original configuration as the cutter position is cycled. Advance the positioning lever to close the cutter and turn off the motor.

Note: The automatic motor control feature of the Cutter Driver can be disabled by using the motor override switch. When the switch is up, the automatic motor control is enabled. When the switch is down, the cutter positioning lever can be advanced and retracted without activating the motor.

4. Inspect the shaft, cutter housing and distal tip for smooth transitions. Do not use the catheter if a sharp edge or protrusion is detected.

CAUTION: Do not sharply bend or kink the catheter shaft during handling as this could damage the device and impair its function.

5. Check the catheter shaft for functionality of the hydrophilic coating. When wetted with sterile saline, the catheter shaft should feel slippery.

Note: To facilitate catheter handling, the proximal most portion of shaft is not coated.

6. Should the catheter become kinked or damaged during use, replace the damaged catheter with a new catheter and return used device to FoxHollow Technologies for evaluation.

Preparation

1. Purge Air From the Catheter.
   a) Fill a syringe (3cc or larger) with heparinized saline.
   b) Attach the syringe to the distal end of the catheter tip and gently inject saline until all air is eliminated from the tip.
   c) Next, flush the catheter shaft by attaching the heparinized saline filled syringe to the catheter flush luer. With the cutter closed, gently apply pressure to the syringe until all air has been flushed from the catheter and saline is seen exiting the cutter.

Insertion and Use

Once prepared, the catheter is ready for insertion into the patient.

1. Insertion
   a) Prepare the patient and administer the appropriate anticoagulant and vasodilator therapy for standard percutaneous intervention.
   b) Insert the appropriate sized sheath and hemostasis valve using standard techniques.

CAUTION: Refer to the Key Catheter Specifications table for appropriate sheath size requirements. Use of sheaths smaller than those recommended may compromise device performance.

   c) Using standard technique, place a guidewire across the target lesion.
   d) Ensure that the cutter positioning lever is in its fully advanced, i.e. closed and off, position. Carefully backload the end of the guidewire through the tip of the SilverHawk Catheter.
   e) Loosen the hemostasis valve and carefully insert the SilverHawk Catheter into the sheath. Retighten the hemostasis valve to prevent blood loss.

CAUTION: Do not over tighten the hemostasis valve as this may inhibit smooth advancement and rotation of the catheter or possibly damage the shaft.

2. Lesion Treatment
   a) Using fluoroscopic guidance, carefully advance the SilverHawk Peripheral Catheter to the proximal edge of the target stenosis.

WARNING: The cutter section of the SilverHawk Peripheral Catheter is a rigid component. Do not use excessive force or torque to advance the SilverHawk Catheter as vessel trauma and/or device failure may result.

WARNING: Do not use the SilverHawk Peripheral Catheter in bends in excess of 90° or if excessive calcification is detected by IVUS or angiography.

Note: If the catheter cannot be advanced across the lesion, it may be necessary to carefully remove the catheter and pre-dilate the lesion with a small diameter balloon angioplasty catheter.

   b) Carefully rotate the SilverHawk Peripheral Catheter blade opening toward the treatment site. Additional angiographic assessment should be performed to confirm catheter position in relation to the lesion.

Note: The cutter housing is radiopaque to facilitate angiographic visualization of the device orientation.

Left

Anterior/Posterior

Right

In addition, a radiopaque ring is located just proximal to the distal most edge of the tip.

CAUTION: If device is not rotating easily, do not torque the catheter shaft more than 360° in one direction. Doing so could result in device failure such as shaft kinking or tip fracture. Device repositioning or lesion predilatation may be required.

   c) To begin plaque excision, retract the cutter positioning lever which will expose the rotating blade and deflect the catheter tip.

Note: When advancing or retracting the positioning lever, the lever must be moved until a "click" is felt at the end of the lever travel. This indicates that the catheter has achieved its FULLY retracted or FULLY advanced position.

WARNING: Operation of the device with the blade partially opened or closed could result in vessel trauma or possible embolization of previously excised tissue.

   d) With the motor running, slowly advance the SilverHawk Catheter through the target lesion under fluoroscopic guidance.

   Reference the following matrix for the length of cut and number of cutting passes that may be completed for each Catalog Number before removing and emptying the device.

Catalog #	Length of Cut	# cuts per insertion
P4056	50 mm	2
P4052	50 mm	2

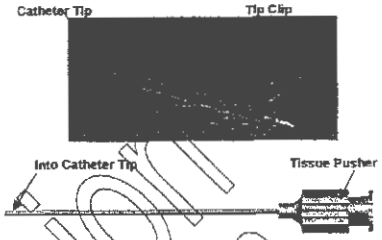
WARNING: The storage capacity of the catheter tip must not be exceeded or embolization of excised tissue fragment may result.

WARNING: If the catheter does not advance easily, close the cutter by advancing the positioning lever. Excessive force should not be used to advance the positioning lever. Device repositioning or predilatation may be required.

   e) Once the end of the target segment is reached, stop advancing the catheter. Carefully advance the cutter positioning lever to close the cutter and turn off the Cutter Driver, this will be indicated by a tactile "click"
   f) At this point, a combination of angiographic and/or intravascular ultrasound imaging should be used to assess the extent of plaque excision.
   g) For models that support multiple cuts per insertion, the catheter may be re-advanced and positioned for additional cuts by repeating steps a) through f). Otherwise, proceed to Catheter Removal and Tissue Removal sections, below.

3. Catheter Removal
   a) The catheter should be carefully removed from the patient under fluoroscopic guidance.
   b) Final angiographic and/or intravascular ultrasound evaluation should be performed post SilverHawk Catheter treatment.

4. Tissue Removal
   a) Fill a syringe (3cc or larger) with saline.
   b) Attach the syringe to proximal luer adapter on the tissue pusher assembly.
   c) Rotate the torque shaft to position the cutter window for optimal viewing.
   d) Retract the cutter positioning lever to expose the cutter within the cutter window. Turn the main power switch on the Cutter Driver to OFF and detach the catheter from the Cutter Driver.
   e) Insert nosecone into the tip clip.
   f) Pinch the tip clip around the nosecone (it will not damage the nosecone).
   g) Insert the tip of the tissue pusher into the catheter vent hole at the distal end of the catheter tip.
   h) Apply pressure to the syringe and slowly advance the tissue pusher to flush tissue from the cutter window.
   i) If any resistance is felt while advancing the tissue pusher, immediately clear the tissue from the cutter window with the tweezers.
   j) Use tweezers to retrieve exposed tissue from the cutter window if it does not fully exit the window.
   k) Repeat above steps as needed to remove tissue.
   l) Once all of the tissue has been removed from the tip, re-flush distal tip reservoir according to the Preparation section, step 1.b.
   m) Release the tip clip and slide it off the nosecone.



Please read this manual and follow its instructions carefully. The words WARNING, CAUTION and NOTE convey special meanings. When they are used throughout this manual, they should be carefully reviewed to ensure the safe and effective operation of this product.

⚠ WARNING: A WARNING indicates that the personal safety of the patient or physician may be involved. Disregarding a WARNING could result in injury to the patient or physician.

CAUTION: A CAUTION indicates that particular service procedures or precautions must be followed to avoid possible damage to the product.

NOTE: A NOTE indicates special information to facilitate use of the product, or to clarify important information.

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. Do not incinerate the Cutter Driver unit, as the enclosed batteries may explode at excessive temperatures.

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular setting. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Consult the manufacturer or field service technician of the equipment experiencing interference for help.
- Warning: There are no user replaceable parts in the Cutter Driver

Contact Information

If you have any questions or comments regarding the use of this product contact:

FoxHollow Technologies
740 Bay Road
Redwood City, CA 94063 USA
Customer Service:
Tel: 877.348.4295 Fax: 888.233.2849
Email: customerservice@foxhollowtech.com

EC REP
MediMark® Europe
11, rue Émile Zola-BP 2332
38033 Grenoble Cedex-2-France

CE 0086

EXHIBIT I

ev3™

TurboHawk™

Peripheral Plaque Excision System

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The TurboHawk™ Peripheral Plaque Excision System (TurboHawk Catheter and Cutter Driver) is designed for the treatment of *de novo* and restenotic atherosclerotic calcified and non-calcified lesions located in native peripheral arteries. When used in complex, hard, calcified lesions, the TurboHawk Catheter should be paired with the SpiderFX™ Embolic Protection Device to mitigate any risk of distal embolization that may be generated by the breakdown of heavily calcified plaque. The TurboHawk Catheter consists of a flexible shaft designed to track over a 0.014" guidewire. At the distal end of the TurboHawk Catheter is a small cutting assembly comprised of a rotating inner blade contained within a tubular housing. The proximal end of the TurboHawk Catheter contains a connector and cutter positioning lever (thumb switch) designed to fit into the Cutter Driver. The Cutter Driver is a handheld, disposable, battery-driven unit (Catalog No. FG-02550), which powers the device. For information about the SpiderFX Embolic Protection Device, reference the Instructions for Use provided with the device.

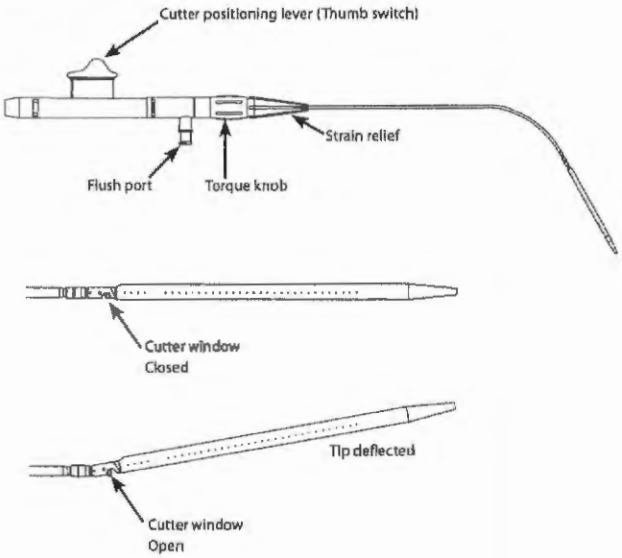
The TurboHawk Peripheral Plaque Excision System has two switches: 1) the Cutter Driver main power switch and 2) the TurboHawk Catheter thumb switch. The Cutter Driver main power switch supplies power to the device when turned ON. The TurboHawk Catheter thumb switch activates the drive shaft and engages the cutter when pulled proximally to the ON position. With the cutter engaged, the TurboHawk Catheter is slowly advanced across the lesion, shaving occlusive material from the artery. The excised tissue is captured and stored in the tip of the device. The cutting process is completed by advancing the TurboHawk Catheter thumb switch distally deactivating the drive shaft and disengaging the cutter. The TurboHawk Catheter thumb switch is fully advanced distally to the OFF position in order to pack the excised plaque into the tip. This cutting sequence is repeated as necessary to achieve the desired degree of plaque excision.

Table 1: Key TurboHawk Catheter Specifications

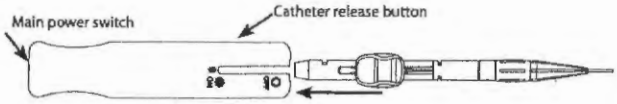
Catalog Number	THS-L5-C	THS-LX-C
Model	L5-C	LX-C
Usable Length	104 cm	104 cm
Tip Length	6.0 cm	9.0 cm
Maximum Catheter Profile	0.105" (2.7mm)	0.105" (2.7 mm)
Minimum Sheath Size	8F	8F
Shape Set	Mechanical	Mechanical
Maximum Guidewire Diameter	0.014"	0.014"
Minimum Vessel Diameter	3.5 mm	3.5 mm

ILLUSTRATION AND NOMENCLATURE

Catheter:



Cutter Driver:



NOTE: The Cutter Driver is protected against electrical shock (defibrillation proof - type CF). Keep the Cutter Driver dry (IPX0). Not suitable for use in the presence of a flammable anesthetic mixture. The Cutter Driver operates in a continuous mode and is internally powered by batteries.

INDICATIONS FOR USE

The TurboHawk Peripheral Plaque Excision System is intended for use in atherectomy of the peripheral vasculature. The TurboHawk Catheter is indicated for use in conjunction with the SpiderFX Embolic Protection Device in the treatment of severely calcified lesions. The TurboHawk Catheter is NOT intended for use in the coronary, carotid, iliac or renal vasculature.

CONTRAINDICATIONS

- Do not use in the coronary arteries
- Do not use in the carotid artery
- Do not use in the iliac or renal vasculature
- Do not use for in-stent restenosis at the peripheral vascular site
- Any evidence or history of intracranial bleeding or aneurysm
- Any history of thrombotic or hemorrhagic stroke
- Known hypercoagulable state or coagulopathy or abnormal bleeding tendency
- Evidence of intraocular hemorrhage by opthalmoscopic exam
- History of thrombocytopenia or thrombocytosis
- Severe trauma, fracture, major surgery or biopsy of a parenchymal organ within the past 3 months
- Prolonged cardiopulmonary resuscitation
- Endoscopic peptic ulcer disease in the past 3 years or gastrointestinal bleeding within the past 3 months
- Genitourinary bleeding within the past 3 months
- Severe persistent hypertension (systolic pressure >180 mmHg)
- Allergy or intolerance to aspirin

WARNINGS

- The TurboHawk Catheter should be paired with the SpiderFX™ Embolic Protection Device when used in complex, hard, calcified lesions to mitigate any risk of distal embolization that may be generated by the breakdown of heavily calcified plaque.
- The TurboHawk Catheter should only be used by physicians trained in percutaneous peripheral interventional procedures.
- Use of this device should be limited to hospitals where surgical support is readily available in the event of a serious complication.
- The TurboHawk Catheter may only be used with the Cutter Driver.
- This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and risk of compromised device performance.
- Do not use the device after the labeled "Use By" expiration date.
- This device is not to be used in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants.
- Always use direct fluoroscopic observation when manipulating the TurboHawk Catheter in the peripheral vessels. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Never advance the distal tip of the TurboHawk Catheter near the floppy end of the guidewire. A TurboHawk Catheter advanced to this position may not follow the guidewire when it is retracted and cause the guidewire to buckle into a loop. If this occurs, the catheter and guidewire should be removed together to prevent potential damage to vessel walls. If resistance is still felt, the sheath should also be removed as part of the unit.
- The cutter section of the TurboHawk Catheter is a rigid component. Do not use excessive force or torque to advance the catheter as vessel trauma and/or device failure may result.
- Do not use the TurboHawk Catheter in bends in excess of 90°. Doing so may result in device failure.
- Operation of the device with the blade partially opened or closed could result in vessel trauma or possible embolization of previously excised tissue.

- When using the TurboHawk Catheter with the SpiderFX Device, never advance the distal tip of the catheter near the SpiderFX Device proximal radiopaque marker band. Contact with the marker band may result in distal embolization of the captured debris, as well as vessel trauma or device failure.
- The storage capacity of the catheter tip must not be exceeded or embolization of excised tissue fragments may result.
- If the SpiderFX Device is not used, exceeding the recommended maximum length of cut and/or number of cut passes prior to removing and emptying the device will increase the risk of embolization of excised tissue fragments.
- If the TurboHawk Catheter does not advance easily, close the cutter by advancing the positioning lever. Excessive force should not be used to advance the positioning lever. Device repositioning or predilatation may be required.
- Avoid excessive movement of the TurboHawk Catheter within the vessel at all times as doing so could result in embolization or vessel damage. In addition, excessive catheter manipulation with the cutter window open could result in embolization of previously excised tissue fragments.

PRECAUTIONS

- Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.
- Do not sharply bend or kink the TurboHawk Catheter shaft during handling as this could damage the device and impair its function.
- Refer to **Table 1** Key TurboHawk Catheter Specifications for appropriate sheath size requirements. Use of sheaths smaller than those recommended may compromise device performance.
- When using the SpiderFX Device in combination with the TurboHawk Catheter, the SpiderFX Filter must be deployed such that the proximal radiopaque marker is no less than 8cm (for LS-C use) or 11cm (for LX-C use) distal to the lesion. Failure to appropriately place the filter may compromise device performance.
- The Guidewire MUST go through BOTH lumens; otherwise, the tip may be open. Operation of the device with the tip open could result in embolization of excised tissue.
- Do not over tighten the hemostasis valve as this may inhibit smooth advancement and rotation of the TurboHawk Catheter or possibly damage the shaft.
- If the device is not rotating easily, do not torque the TurboHawk Catheter shaft more than 360° in one direction. Doing so could result in device failure such as shaft kinking or tip fracture. Device repositioning or lesion predilatation may be required.
- Cutting extended lengths in severely calcified lesions may result in cutter wear. If increased resistance is encountered during a cutting pass, this may indicate that the device needs to be replaced.

POTENTIAL COMPLICATIONS / ADVERSE EVENTS

Potential adverse events associated with use of this device and other interventional catheters include, but are not limited to the following:

- Amputation
- Aneurysm
- Arterial dissection
- Arterial perforation
- Arterial rupture
- Arterial spasm
- Arteriovenous fistula
- Bleeding complications
- Death
- Embolism and/or arterial thrombosis
- Emergency or non-emergency arterial bypass surgery
- Entry site complications
- Hypotension
- Infection
- Ischemia
- Restenosis of the treated segment
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair

SUMMARY OF DEFINITIVE CA^{++} STUDY

DEFINITIVE Ca^{++} was a prospective, multi-center, non-randomized, single-arm study to evaluate the safety and effectiveness of the SilverHawk™/TurboHawk™ Peripheral Plaque Excision Systems and the SpiderFX™ Embolic Protection Device for the treatment of moderate to severely calcified peripheral arterial disease in the superficial femoral and/or popliteal arteries. An independent Angiographic Core Laboratory and a Clinical Events Committee (CEC) were employed to ensure unbiased review and classification of events and endpoints. 133 subjects from 17 centers were enrolled. A summary of safety and effectiveness data is provided in the following table.

Table 2: DEFINITIVE Ca^{++} Summary of Safety and Effectiveness

Parameters	Results	
	Site Reported	Angiographic Core Laboratory Reported
Baseline Demographics		
Age (mean ± SD)	69.7 ± 9.8	
Male	71.4% (95/133)	
Severe calcification		81.0% (136/168)
Reference vessel diameter (mm) (mean ± SD (N))		4.9 ± 0.9 (168)
Target lesion length (mm) (mean ± SD (N))		39.0 ± 27.0 (168)
Pre-procedure diameter stenosis (%) (mean ± SD (N))		76.5 ± 15.4 (168)
Primary Effectiveness Endpoint		
Successful revascularization (≤ 50% residual diameter stenosis following plaque excision)	97.0% (162/167)	92.0% (150/163)
Primary Safety Endpoint (Per Angiographic Core Laboratory Review and CEC Adjudication)		
30-day MAE-Free rate	93.1% (122/131)	
Death	0.0% (0/131)	
Acute myocardial infarction	0.8% (1/131)	
Dissection, target vessel (C)	0.0% (0/131)	
Dissection, target vessel (grade D or greater)	0.8% (1/131)	
Clinical perforation, target vessel	2.3% (3/131)	
Pseudoaneurysm, target vessel	0.0% (0/131)	
Thrombosis, target vessel	0.8% (1/131)	
Distal embolism	2.3% (3/131)	
Amputation, above metatarsal line	0.0% (0/131)	
Clinically-Driven Target Vessel Revascularization	0.0% (0/131)	

The proportion of subjects event-free (per Angiographic Core Laboratory review and CEC adjudication) after 30 days was compared to a performance goal of 85.5% based on the TALON registry. The 30-day freedom from MAE rate was 93.1% (122/131). The 95% lower confidence limit was 88.3% (as calculated by the Exact method), greater than the performance goal of 85.5%. Therefore, the primary safety endpoint was met as assessed by the Angiographic Core Laboratory.

The primary effectiveness endpoint was successful revascularization of the target vessel (defined as less than or equal to 50% residual diameter stenosis following plaque excision), as adjudicated by the angiographic core laboratory. The proportion of lesions meeting this criterion was compared to a performance goal of 90.0% based on the TALON registry. Percent residual diameter stenosis results from the TALON registry were based on site-reported data. Per angiographic core laboratory assessment, the primary effectiveness criterion (≤ 50% residual diameter stenosis) was achieved in 92.0% (150/163) of lesions. The lower bound of the confidence interval is 87.6%. Therefore, the effectiveness endpoint was not met.

The protocol mandated the use of an independent angiographic core laboratory to apply consistency and an unbiased assessment to residual diameter stenosis; however, the primary effectiveness performance goal was based on site-reported residual diameter stenosis from the TALON registry. The differences between site-assessed residual diameter stenosis data and angiographic core laboratory-assessed residual diameter stenosis data that were seen in this study are consistent in direction and magnitude with other studies.[2,3]

Per site assessment, the primary endpoint success criterion was achieved in 97.0% (162/167) of lesions. The lower bound of the confidence interval is 93.8%, which is above the 90% performance goal that was derived from the TALON site-reported data.

Sources:

[1] Ramiah et al. J Endovasc Ther 2006;13:592-602.

[2] Popma et al. *Am J Cardiol* 80: 19K-25K, 1997.

[3] Werk et al. *Circulation* 118: 1358-1365, 2008.

HOW SUPPLIED

The TurboHawk Catheter and Cutter Driver are packaged and sterilized individually, but shipped in a single shelf carton. Both are intended for single patient use only.

STORAGE AND USE CONDITIONS

Store sterile packaged TurboHawk Catheters and Cutter Drivers in a cool dry place until ready to use. Do not expose to organic solvents, ionizing radiation, ultraviolet light or alcohol-based fluids.

DIRECTIONS FOR USE

INSPECTION

1. Prior to use, carefully inspect the TurboHawk Catheter and Cutter Driver to verify that neither the sterile packaging nor the devices themselves have been damaged.
2. Connect the TurboHawk Catheter to the Cutter Driver by inserting the proximal end of the catheter into the motor. Ensure the cutter positioning lever aligns with the slot in the Cutter Driver. When fully inserted, the catheter connector will lock into the Cutter Driver. To remove the catheter from the Cutter Driver, depress the catheter lock release button and pull the catheter from the motor.

   NOTE: To avoid accidental activation of the Cutter Driver, be sure the cutter positioning lever is in the fully forward position prior to insertion into the Cutter Driver.
3. To confirm functionality of the TurboHawk Catheter, advance and retract the cutter positioning lever. Ensure that the motor turns on and off automatically and that the inner blade moves freely. The catheter tip should deflect and return to its original configuration as the cutter position is cycled. Advance the positioning lever to close the cutter window and turn the motor to OFF.

   NOTE: The automatic motor control feature of the Cutter Driver can be disabled by using the motor override switch. When the switch is up, the automatic motor control is enabled. When the switch is down, the cutter positioning lever can be advanced and retracted without activating the motor.
4. Inspect the shaft, cutter housing and distal tip for smooth transitions. Do not use the catheter if a sharp edge or protrusion is detected.

   CAUTION: Do not sharply bend or kink the catheter shaft during handling as this could damage the device and/or impair its function.
5. Check the catheter shaft for functionality of the hydrophilic coating. When wetted with sterile saline, the catheter shaft should feel slippery.

   NOTE: To facilitate catheter handling, the proximal most portion of shaft is not coated.
6. Should the catheter become kinked or damaged during use, replace the damaged catheter with a new catheter and return used device to ev3 Inc. for evaluation.

PREPARATION

1. **Purge Air from the Catheter.**
   a. Fill a syringe (3cc or larger) with heparinized saline.
   b. Ensure the main power switch on the end of the Cutter Driver is turned to the OFF position. Retract the cutter positioning lever to the ON position to expose the cutter within the cutter window.
   c. To flush the catheter shaft, attach the syringe to the catheter flush port. Gently apply pressure to the syringe until all air has been removed and saline is seen exiting the cutter window.
   d. Fully advance the cutter positioning lever to the OFF and closed position.
   e. Submerge the Tissue Flushing Tool (TFT) in saline to lubricate the inner diameter.
   f. Submerge the catheter tip in saline to activate the hydrophilic coating.
   g. Fully advance the cutter positioning lever to the OFF and closed.
   h. Loosen the TFT hemostasis valve and slide the TFT onto the distal end of the catheter tip. Position the TFT luer over the cutter window. Tighten the TFT down onto the catheter.
   i. Fill a syringe (10cc recommended) with saline and attach the syringe to the luer on the TFT.
   j. Attach the filled syringe to the luer on the TFT.
   k. Rotate the distal end of the tip to open.
   l. Retract the cutter positioning lever to the ON position to expose the cutter within the cutter window.
   m. Flush the tip until fluid exits the distal end of the tip.
   n. Fully advance the cutter positioning lever to the closed and OFF position.
   o. Rotate the distal end of the tip to close.
   p. Loosen the TFT, slide it distally and remove from the tip of the catheter.
   q. Turn the main power switch of the Cutter Driver to ON.

INSERTION AND USE

Once prepared, the catheter is ready for insertion into the patient.

1. **Insertion**
   a. Prepare the patient and administer the appropriate anticoagulant and vasodilator therapy for standard intervention.
   b. Insert the appropriate sized sheath and hemostasis valve using standard techniques.

      CAUTION: Refer to Table 1 Key TurboHawk Catheter Specifications for appropriate sheath size requirements. Use of sheaths smaller than those recommended may compromise device performance.
   c. Angiographic assessment of the vessel should be performed to locate the target lesion.
   d. If severe calcium is detected in the treatment area, the SpiderFX Embolic Protection Device should be used in conjunction with the TurboHawk Catheter. Refer to the SpiderFX Embolic Protection Device Instructions for Use for appropriate filter sizing and deployment instructions.

      CAUTION: When using the SpiderFX Device in combination with the TurboHawk Catheter, the SpiderFX filter must be deployed such that the proximal radiopaque marker is no less than 8cm (for LS-C use) or 11cm (for LX-C use) distal to the lesion. Failure to appropriately place the filter may compromise device performance.
   e. Using standard technique, place a guidewire across the target lesion. If using the SpiderFX Device, the capture wire will act as the primary guidewire for the TurboHawk Catheter.

      NOTE: The minimum vessel diameter for the TurboHawk Catheter is 3.5mm.
   f. Ensure that the cutter positioning lever is in its fully advanced position, i.e. closed and OFF position.
   g. Carefully backload the end of the guidewire through the tip of the TurboHawk Catheter, making sure the guidewire travels through BOTH guidewire lumens and exits proximal to the cutter.

      CAUTION: The guidewire MUST go through BOTH lumens, otherwise, the tip may be open. Operation of the device with the tip open could result in embolization of excised tissue.
   h. Loosen the hemostasis valve and carefully insert the TurboHawk Catheter into the sheath. Retighten the hemostasis valve to prevent blood loss.

      CAUTION: Do not over tighten the hemostasis valve as this may inhibit smooth advancement and rotation of the catheter or possibly damage the shaft.
2. **Lesion Treatment**
   a. Using fluoroscopic guidance, carefully advance the TurboHawk Catheter to the proximal edge of the target stenosis.

WARNING: The cutter section of the TurboHawk Catheter is a rigid component. Do not use excessive force or torque to advance the catheter as vessel trauma and/or device failure may result.

WARNING: Do not use the TurboHawk Catheter in bends in excess of 90°. Doing so may result in device failure.

NOTE: If the TurboHawk Catheter cannot be advanced across the lesion, it may be necessary to carefully remove the TurboHawk Catheter and pre-dilate the lesion with a small diameter balloon angioplasty catheter.

b. Carefully rotate the TurboHawk Catheter blade opening toward the treatment site. Additional angiographic assessment should be performed to confirm catheter position in relation to the lesion.

NOTE: The cutter housing is radiopaque to facilitate angiographic visualization of the device orientation.


Left


Anterior/Posterior


Right

In addition, a radiopaque ring is located just proximal to the distal most edge of the tip.

CAUTION: If TurboHawk Catheter is not rotating easily, do not torque the catheter shaft more than 360° in one direction. Doing so could result in device failure such as shaft kinking or tip fracture. Device repositioning or lesion predilatation may be required.

c. To begin plaque excision, retract the cutter positioning lever which will expose the rotating blade and deflect the catheter tip.

NOTE: When advancing or retracting the positioning lever, the lever must be moved until a "click" is felt at the end of the lever travel. This indicates that the catheter has achieved its FULLY retracted or FULLY advanced position.

WARNING: Operation of the device with the blade partially opened or closed could result in vessel trauma or possible embolization of previously excised tissue.

d. With the motor running, slowly advance the TurboHawk Catheter through the target lesion under fluoroscopic guidance.

WARNING: When using the SpiderFX Device in combination with TurboHawk Catheter, never advance the distal tip of the TurboHawk Catheter near the SpiderFX Device proximal radiopaque marker band. Contact with the marker band may result in distal embolization of the captured debris, as well as vessel trauma or device failure.

Reference the following matrix for the length of cut and number of cutting passes that may be completed for each Catalog Number before removing and emptying the device.

Catalog #	Length of Cut	# Cuts per Insertion*
THS-LS-C	50 mm	1
THS-LX-C	75 mm	1

* If the SpiderFX Device is used, multiple cuts may be made per insertion.

WARNING: The storage capacity of the TurboHawk Catheter tip must not be exceeded or embolization of excised tissue fragments may result.

WARNING: If the SpiderFX Device is not used, exceeding the recommended maximum length of cut and/or number of cut passes prior to removing and emptying the device will increase the risk of embolization of excised tissue fragments.

NOTE: If using the SpiderFX Device, it should be frequently observed under fluoroscopy to verify that the filter has not become occluded with debris, resulting in slow/no-flow. If the filter becomes occluded or flow is compromised, the TurboHawk Catheter should be removed and the filter recovered. Once recovered, the filter cannot be reintroduced into the body. A new filter should be deployed per the SpiderFX Embolic Protection Device Instructions for Use.

WARNING: If the catheter does not advance easily, close the cutter by advancing the positioning lever. Excessive force should not be used to advance the positioning lever. Device repositioning or predilatation may be required.

e. Once the end of the target segment is reached, stop advancing the catheter. Carefully advance the cutter positioning lever to close the cutter and turn off the Cutter Driver, this will be indicated by a tactile "click".

f. At this point, a combination of angiographic and/or intravascular ultrasound imaging should be used to assess the extent of plaque excision.

NOTE: If using the SpiderFX Device, verify that the filter has not become occluded with debris, prior to making additional cutting passes with the TurboHawk Catheter.

g. If the SpiderFX Device is used, multiple cuts can be made per insertion. The TurboHawk Catheter may be re-advanced and positioned for the additional cut by repeating Steps a) through f) if there is adequate storage capacity remaining in the tip (see note below).

NOTE: If the positioning lever cannot be fully advanced (after completing a cut) the tip may be at full capacity. Proceed to the Catheter and Tissue Removal sections.

3. **Catheter Removal**

a. The catheter should be carefully removed from the patient under fluoroscopic guidance.

b. Final angiographic and/or intravascular ultrasound evaluation should be performed post TurboHawk Catheter treatment.

4. **Tissue Removal**

a. Off load the catheter from the 0.014" guidewire.

b. Fully advance the cutter positioning lever to the closed and OFF position. Turn the main power switch on the Cutter Driver to OFF.

c. Slide the Tissue Flush Tool (TFT) onto the distal end of the catheter tip and position the TFT luer over the cutter window. Tighten the TFT down onto the catheter.

d. Fill a syringe (10cc recommended) with saline and attach the syringe to the luer on the TFT.

e. Rotate the distal end of the tip to open.

f. Retract the cutter positioning lever to expose the cutter within the cutter window.

g. To reduce spray during flushing, place the tip under gauze.

h. Flush the tip with one, constant stroke of 5-10cc/sec.. (Repeat if necessary.)

i. Use tweezers to retrieve exposed tissue from the flush window if it does not fully exit the window.

j. Ensure the cutter positioning lever is in its fully advanced position, i.e. closed and OFF.

k. Rotate the distal end of the tip to close.

l. Loosen the TFT, slide it distally and remove from the tip of the catheter.

m. Turn the main power switch on the Cutter Driver to ON.

5. **Repeated Insertion and Use**

a. If additional insertions are to be made, repeat from the Insertion and Use section, Step 1c.

b. This cutting sequence can be repeated as necessary to achieve the desired degree of plaque excision.

NOTE: In vitro testing in severely calcified cadaver lesions has demonstrated minimal cutter wear after cutting calcified lesions totaling 500mm in length. Device performance was maintained throughout testing.

CAUTION: Cutting extended lengths in severely calcified lesions may result in cutter wear. If increased resistance is encountered during a cutting pass, this may indicate that the device needs to be replaced.

ABOUT THIS MANUAL

Please read this manual and follow its instructions carefully. The words WARNING, CAUTION and NOTE convey special meanings. When they are used throughout this manual, they should be carefully reviewed to ensure the safe and effective operation of this product.

WARNING: A WARNING indicates that the personal safety of the patient or physician may be involved. Disregarding a WARNING could result in injury to the patient or physician.

CAUTION: A CAUTION indicates that particular service procedures or precautions must be followed to avoid possible damage to the product.

NOTE: A NOTE indicates special information to facilitate use of the product, or to clarify important information.

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. Do not incinerate the Cutter Driver unit, as the enclosed batteries may explode at excessive temperatures.

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular setting. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Consult the manufacturer or field service technician of the equipment experiencing interference for help.

WARNING: There are no user replaceable parts in the Cutter Driver

The Batteries Directive, 2006/66/EC, introduces new requirements, effective September 26, 2008, regarding removability of batteries from waste equipment in EU Member States. To comply with this Directive, this device has been designed for safe removal of the batteries at end-of-life by a waste treatment facility. Infected units should be de-contaminated before they are sent for recycling. In the event that it is not possible to decontaminate the unit for recycling, the hospital should not attempt to remove the batteries from waste equipment. Continued disposal of small amounts of portable batteries to landfill and incineration is allowed under the Batteries Directive and Member State regulations.

WARRANTY DISCLAIMER

Although this product has been manufactured under carefully controlled conditions, ev3 Inc. has no control over the conditions under which this product is used. ev3 Inc. therefore disclaims all warranties, both express and implied, with respect to the product including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ev3 Inc. shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind ev3 Inc. to any representation or warranty with respect to the product.

The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

THIS PAGE INTENTIONALLY LEFT BLANK

DEFINITION OF SYMBOLS

	Main power ON		Secondary power ON
	Main power OFF		Secondary power OFF
	Catheter lock release		
	Defibrillation-proof, type CF applied part		
STERILE EO	Sterilized using ethylene oxide gas		
STERILE R	Sterilized using irradiation		
	Caution		
	Manufacturer		Date of Manufacture
REF	Catalogue Number	LOT	Batch Code
EC REP	Authorised representative in the European community	Rx Only	For prescription use only
	Keep Dry		Keep away from sunlight
	Use By		Do not reuse
	Do not use if package is damaged		Consult instructions for use
	Telephone	FAX	Facsimile

Contact Information

If you have any questions or comments regarding the use of this product contact:

ev3 Corporate World Headquarters
Peripheral Vascular
3033 Campus Drive
Plymouth, MN 55441
USA

Rx Only

Manufactured at:
Irvine, CA

+1.763.398.7000
+800.716.6700
FAX +1.763.398.7200

www.ev3.net

501085-001A JAN/12

EXHIBIT J

SilverHawk - US Certification

SILVERHAWK Certification

TM/RM Name: Rick Ponder

Date: 2-19-10

ev3

1		**Demonstrate and describe set up of device** 1. Insert proximal end of catheter into cutter driver and lock into place 2. Turn power switch ON at back of cutter driver. 3. Pull back Thumb-switch to 'ON' position and test cutter for exposure and hinging 4. Turn power switch OFF at back of cutter driver 5. Flush catheter shaft by attaching 3cc syringe with heparinized saline to catheter flush luer 6. Backflush guidewire lumen 7. Turn power switch to 'ON' at back of cutter driver and Advance Thumbswitch to 'OFF' position.
1		**Demonstrate and describe set up of device** 8. Unscrew Tissue Flushing Tool (TFT), slide it down catheter to cover cutter housing, then tighten 9. Rotate the distal tip to the OPEN position 10. Pull back Thumb-switch to 'ON' position and Turn power switch 'OFF' at back of cutter driver 11. Flush TFT with 3cc syringe with heparinized saline 12. Turn power switch to 'ON' at back of cutter driver and Advance Thumbswitch to 'OFF' position. 13. Unscrew TFT and slide back to proximal end of catheter
1		**Demonstrate and describe steps for cleaning of non-flush device TISSUE PUSHER** (Note: non-flush, L&M Series only, can be cleaned on wire) 1. Pull back Thumb switch to ON position to expose cutter and turn power OFF at back of cutter 2. Insert tissue pusher into catheter vent hole at distal end 3.Attach 3cc syringe to tissue pusher. Flush tissue from cutter window 4. Use tweezers (if necessary) to retrieve exposed tissue from cutter 5. Repeat steps 3-4 if necessary 6. Turn power switch on and turn thumbswitch to OFF position
1		**Demonstrate and describe steps for cleaning of FLUSH DEVICE** 1. Remove catheter from guidewire 2. Unscrew Tissue Flushing Tool (TFT), slide it down catheter to cover cutter housing, then tighten 3. Pull back Thumbswitch to 'ON' position and power to OFF at back of cutter 4. Rotate distal tip to OPEN position 5. Insert tip into Tissue Collection Vial 6. Flush tip with one fast stroke using 3cc syringe 7. Repeat step 6 if necessary 8. Remove vial when flushing complete 9. Close distal tip then flush 10. Turn power switch ON and thumbswitch OFF 11. Rotate distal tip to close window (realign guidewire lumen)
1		**Demonstrate and describe steps for cleaning of non-flush TISSUE REMOVAL DEVICE** 1. Turn thumbswitch ON and power Off at back of cutter 2. Insert the catheter tip into the distal opening of the TRD and through black valve 3. Attach 3cc syringe to proximal luer adaptor on Tissue Removal Device (TRD) 4. Use tweezers to retrieve exposed tissue from the cutter window if necessary 5. Turn power switch ON and thumbswitch to OFF

When complete fax to Connie McComb @763-398-7200

X:\Marketing\MKT\IISales Training_Market Development\Training Certificates\2008 Certifications

114384-001 (C) Feb 09

RICK PONDER – OVER PHOTOCOPIED TEMPLATE

VERBAL CERTIFICATION

1. Detail Prep for the following four SilverHawk catheters-
   TurboHawk LS-M or MS-M
   SXL/EXL SS+/ES+

2. Detail cleaning procedure for the following four SilverHawk catheters-
   TurboHawk LS-M or MS-M
   SXL/EXL SS+/ES+

3. Explain the continuum of care.
   Correct ✓ Incorrect ____

4. Why is it important to operate SilverHawk at the correct forward speed?
   Correct ____ Incorrect ____
   a. Decreases potential for distal embolic events
   b. Ensures optimal tissue capture (more efficient cutting, tests show slower rpms are smoother and more efficient)
   c. Helps maintain cutter contact with lesion so it doesn't skip across plaque

5. Explain the difference between the "urge" and the jog.
   Correct ✓ Incorrect ____
   a. The jog is the bend in the catheter, the urge is what applies force to the vessel wall when the SilverHawk is activated

6. What size vessel does an MS-M treat?
   Correct ____ Incorrect ____
   a. 3.5 – 5.0 mm

7. Name two differences between an SXL and SS+
   Correct ____ Incorrect ____
   a. Length of nosecone (7.2 cm vs. 2.6cm)
   b. Packing vs. non packing device
   c. Addl. MEC length of cut, amount of debris

   +1/2

8. If a physician chooses to use SilverHawk to treat in-stent restenosis, what should they do if it gets caught on a stent strut? What should thy not do?
   Correct ____ Incorrect ____
   a. Do not pull off. Try to rotate off the stent while cutting. Turn on or back off device not with the thumb switch

   -1/2

9. Why should we commit to pre-case planning?
   Correct ____ Incorrect ____
   a. Allows you to participate as a partner in the case
   b. Helps control variables during the case
   c. Sets reasonable expectations for success

10. What information can you learn form the initial angiographic assessment?
Correct ____ Incorrect ____
[redacted]

11. Name two reasons it is good idea to shoot an angiogram all the way to the foot after a SilverHawk procedure?
Correct ____ Incorrect ____
[redacted]

12. List three clinical scenarios where a physician may choose to use embolic protection.
Correct ____ Incorrect ____
[redacted]

13. If you have a 90% stenosis in the popliteal artery, what catheter would you use and why?
Correct ____ Incorrect ____
[redacted]

14. If the doctor chooses to use a balloons to predil in the previous case, what size balloon would you recommend?
Correct ____ Incorrect ____
a. [redacted]

15. When operating in calcium, the operator may encounter difficulties when attempting to engage the driver after packing. This is evidenced by the fact the cutter and thumbswitch will not come all the way back and the cutter will not fully emerge and engage. What may be the culprit? What solutions can you offer?
Correct ____ Incorrect ____
[redacted]

16. What conversation would you have with a physician who is contemplating using CSI on a CLI patient?
Correct ____ Incorrect ____
[redacted]

EXHIBIT K

PV SALES TERRITORY MANAGER PERFORMANCE ASSESSMENT 2011

Field Sales Trainer: Rick Ponder **Region: So Cal** **Date: 11-20-11**

INSTRUCTIONS: Insert rating (1, 2, 3, 4, 5) for each question. Suggest that both the TM and also the RM complete the review separately. Manager and TM discuss results, strengths and areas of development.

(5) Outstanding = TM's performance is exceptional and is a role model
(4) Exceeded = TM achieves and sometimes exceeds expectations
(3) Achieved = TM consistently performs as expected
(2) Partially Achieved = TM is progressing toward expected performance
(1) Not Achieved = TM's performance does not meet expectations

QUALITATIVE RESULTS

LEADERSHIP	Self Rating	Manager Rating
Consistently meets/exceeds sales quota every quarter and year	5	0
Consistently grows at or above market year over year at a better than the average rate	5	0
Demonstrates a genuine concern and caring for the success of ev3 as a company	5	0
Model of professional behavior and leadership values in all internal/external interactions	5	0
Team player with fellow TMs, HSs, Sales Leadership, and other ev3 functional groups	5	0
LEADERSHIP - *AVERAGE RATING*	**5.00**	**0.00**

SELLING SKILLS	Self Rating	Manager Rating
Leads with Atherectomy as a standard of care in accounts (PAD Curriculum of Care)	4	0
Ability to use Silverhawk to pull through Stent, PTA and Embolic Protection business	5	0
Can effectively engage customers and overcome their objections	5	0
Effectively builds consensus, gains appropriate commitments and closes business	5	0
Sells the entire bag of products consistently	5	0
SELLING SKILLS - *AVERAGE RATING*	**4.80**	**0.00**

CLINICAL SKILLS/PRODUCT KNOWLEDGE	Self Rating	Manager Rating
Knows how to talk any physician through the conceptual sell on SilverHawk in a way that overcomes a clinical objection (PAD Continuum of Care)	5	0
Able to have the clinical conversation about the advantages of Silverhawk, ATK & BTK	5	0
Runs an effective product evaluation protocol that leads to conversions	5	0
Understands how to position the PV Product line within the PAD Continuum of Care	5	0
Aggressively keeps up on product knowledge and competitor information	5	0
CLINICALS SKILLS/PRODUCT KNOWLEDGE - *AVERAGE RATING*	**5.00**	**0.00**

BUSINESS ACUMEN/CONTRACTS	Self Rating	Manager Rating
Develops and executes accurate and on-going sales plan to achieve sales objectives	5	0
Effectively uses contracts to drive high compliance and pull through other products	4	0
Drives strong pricing practices and discipline in accounts that result in strong ASP's	5	0
Understands national contracts and uses them to drive local IDN agreements	4	0
Delivers great business reviews that result in uncovering other opportunities	4	0
BUSINESS ACUMEN - *AVERAGE RATING*	**4.40**	**0.00**

SILVERHAWK FLIGHT PLAN/MARKET DEVELOPMENT	Self Rating	Manager Rating
Highly skilled in targeting and developing "Hawkers"	5	0
Understands how to position SH within the PAD Continuum of Care (Develops the Clinical Need for SH)	5	0
Effectively plans cases with physicians and manages expectations (Pre-Case Planning), and improves outcomes when supporting cases (In-Case Support)	5	0
Effectively understands the use of internal and external screening programs and when to target appropriately for each (Referral Marketing)	5	0
Effectively plans and manages Referral Marketing resources to drive expected outcomes	4	0
SILVERHAWK FLIGHT PLAN - *AVERAGE RATING*	**4.80**	**0.00**

STANDARDS of BUSINESS ACCOUNTABILITY	Self Rating	Manager Rating
Conducts business transactions in accordance with ev3's compliance guidelines	5	0
Complies with the ev3 Expense Management & T/E policies	5	0
Sets initial consignment levels appropriately and reviews volumes/turns quarterly	5	0

PV SALES TERRITORY MANAGER PERFORMANCE ASSESSMENT 2011			ev3
Field Sales Trainer: Rick Ponder	**Region: So Cal**	**Date: 11-20-11**	
Effectively manages trunk stock and stays within guidelines		5	0
Responds to company requests and completes reports/audits in a timely fashion		5	0
STANDARDS OF BUSINESS ACCOUNTABILITY - *AVERAGE RATING*		**5.00**	**0.00**
QUALITATIVE TOTAL AVERAGE RATING of ALL CATEGORIES		**4.83**	**0.00**

QUANTITATIVE RESULTS

INSTRUCTIONS: Insert rating (1, 2, 3, 4, 5) for each question. Include comments as needed.

(5) Outstanding = Above 115% to quota **(2) Partially Achieved** = 90% to 97.9% to quota

(4) Exceeded = 100.1% - 114.9% to quota **(1) Not Achieved** = Below 90% to quota

(3) Achieved = 98% - 100% to quota Remove the number if not active for the full quarter

% TO ATHERECTOMY QUOTA				
% to plan - Q1 Atherectomy	**Comments**	**114%**	4	0
% to plan - Q3 Atherectomy	Comments:	119%	5	0
% to plan - Q4 Atherectomy	Comments:	114%	4	0
		% to ATHERECTOMY QUOTA - *AVERAGE RATING*	**4.33**	**0.00**
% TO PV PRODUCTS QUOTA				
% to plan - Q2 PV	Comments:	100%	4	0
% to plan - Q3 PV	Comments:	94%	2	0
% to plan - Q4 PV	Comments:	108%	4	0
		% to PV PRODUCTS QUOTA - *AVERAGE RATING*	**3.33**	**0.00**
% TO OVERALL QUOTA				
% to plan Q2	Comments:	107%	4	0
% to plan Q3	Comments:	106%	4	0
% to plan Q4	Comments:	108%	4	0
		% TO OVERALL QUOTA - *AVERAGE RATING*	**4.00**	**0.00**
		QUANTITATIVE TOTAL AVERAGE RATING of ALL CATEGORIES	**3.89**	**0.00**
Overall 2011 PERFORMANCE RATING				
		OVERALL QUALITATIVE RATING	1.21	0.00
		OVERALL QUANTITATIVE RATING	2.92	0.00
		FINAL 2011 PERFORMANCE RATING	**4.13**	**0.00**

PV SALES TERRITORY MANAGER PERFORMANCE ASSESSMENT 2011

Field Sales Trainer: Rick Ponder **Region: So Cal** **Date: 11-20-11**

COMMENTS

Other comments (include relevant items such as position within stack ranking, dollar growth and other aspects that contribute to the overall performance):

Developed key strategies with every rep in So Cal to achieve quota in PV and PE. All So Cal Reps and Hawk Specialists made or exceeded quota

List three areas of strength (support with examples).

Hard working - Team Player - Motivational and Inspirational to Teammates - Executing Workable Strategies with each Rep

List two areas for development and agree upon a time frame for follow-up (Specific, Measureable, Attainable, Realistic). What resources are needed?

Develop more thought leaders and KOL's - Driving Compliance with IDN Contracts

SIGNATURES

Employee's Signature: Certifies discussion occurred – not necessarily agreement Date:

Manager's Signature: Date:

PV SALES TERRITORY MANAGER PERFORMANCE ASSESSMENT 2011			
Field Sales Trainer: Rick Ponder	**Region: So Cal**	**Date:**	**11-20-11**
Human Resources:		Date:	

EXHIBIT L